

No. 92-341V
(Filed: November 21, 1997)

Christian Rhys Vant Erve, a minor, *
by and through his next friends, *
Ron Vant Erve and Cathy Vant Erve, *
Petitioners, *

Childhood Vaccine Injury Act;
exclusion of evidence; abuse
of discretion; production of
records.

v. *

Secretary of Health and Human *
Services, *
Respondent. *

***** 0 *

A. Leroy Toliver, Atlanta, Georgia, for petitioners.

Michael P. Milmo, Washington, D.C., for respondent.

OPINION

BRUGGINK, Judge.

This case comes before the court on respondent's motion for review of the Special Master's June 27, 1997, decision directing the entry of judgment awarding compensation to petitioners under the National Childhood Vaccine Injury Act of 1986, 42 U.S.C. §§ 300aa-1 through 300aa-34 (1994) (the Act). Oral argument was held on October 28, 1997. For the reasons set forth below, the decision of the Special Master is reversed and the matter remanded for a new decision on liability and, if appropriate, damages.

BACKGROUND

Petitioners filed their petition for compensation under the Act on May 14, 1992, for injuries to their son, Christian Rhys Vant Erve, arising allegedly from a diphtheria-pertussis-tetanus (DPT) inoculation he received when he was two-months old. Christian was born on April 27, 1989, and received a DPT inoculation on June 23, 1989. Two days later, he experienced two episodes where "his left arm and leg shook." The seizures continued through the following day, June 26, 1989, prompting Christian's parents to take him to the hospital, where he was admitted. After being diagnosed with seizures and given anti-seizure medication, the seizures stopped and Christian was discharged.

Christian did not exhibit any further seizures after June 1989. By December 7, 1990, however, it became apparent that Christian's development was delayed. Since that time Christian has suffered from severe physical and mental problems, including spastic diplegia, a neurological condition that results in severe stiffness of limbs on both sides of his body. He possesses diminished mental capacity and diminished hearing and visual capacities connected with his neurological condition.

Petitioners alleged that Christian suffered either or both of the table injuries residual seizure disorder⁽¹⁾ and encephalopathy⁽²⁾ within three days of inoculation. Petitioners also alleged that Christian's present physical and mental conditions were sequelae of either or both table injuries.

Respondent filed her report in response to the petition on September 8, 1992, recommending against an award for Christian under the Act. In her report, respondent noted that additional medical records were required to further evaluate the petition.⁽³⁾ Respondent received the requested information. Respondent presented a report from her expert, Dr. Arnold D. Gale, a pediatric neurologist, on December 4, 1992. Dr. Gale's report concluded:

Christian suffers from a chronic static neurologic disorder characterized by spastic diplegia and delayed development, most probably caused by a prenatal cerebral insult.

....

... The medical record provides no evidence that he sustained an acute encephalopathy from any cause; rather, he appears to have experienced a prenatal injury based upon his neuroimaging and clinical course.

(Resp't Pre-hr'g Mem., Witness List, and Ex. List, Ex. 4 at 2.) At the time respondent argued that Christian's condition was caused by a prenatal injury rather than the DPT vaccination.

An affidavit of Dr. Jan Mathisen, Christian's treating pediatric neurologist and petitioners' expert, was filed by petitioners on June 11, 1993. In the affidavit, Dr. Mathisen refers to a magnetic-resonance-imaging (MRI) scan performed in December 1991 and a follow-up study performed in August 1992.⁽⁴⁾ (See Mathisen Aff. ¶ 5.) Dr. Mathisen concludes:

I have reviewed the report from Dr. Gayle [sic] and believe a conclusion of perinatal injury in this child is speculative. There is no clear cut etiology for the seizures. Most children I have seen have demonstrated some clinical finding of cerebral palsy prior to 12-18 months of age when they have perinatal problems. I carefully followed Christian for evidence of spasticity or cerebral palsy and did not see early signs until he was 19 months of age. Additionally, the APGARS and benign neonatal and perinatal course would further militate against a prenatal or perinatal injury.

... It is entirely reasonable in my [sic] opinion to state Christian's present condition is a continuation of

the June, 1989 injury.

(Mathisen Aff. ¶¶ 7-8.)

After a number of unsuccessful settlement discussions, an evidentiary hearing was scheduled for May 26, 1994, where both petitioners and respondent presented evidence through witnesses.⁽⁵⁾ The Special Master ruled in favor of petitioners on the issue of entitlement on June 21, 1994. Specifically, the Special Master found that: (1) petitioners demonstrated that Christian suffered a table-enumerated seizure disorder with residual effects lasting more than six months from his inoculation; (2) respondent failed to demonstrate that the seizure disorder was the result of a "factor unrelated to the administration of the vaccine"; (3) petitioners also demonstrated that Christian suffered a table-enumerated encephalopathy; and (4) respondent failed to demonstrate that the encephalopathy was the result of a "factor unrelated to the administration of the vaccine." See Vant Erve v. Secretary of Health & Human Servs., No. 92-341V (Ct. Fed. Cl. Spec. Master filed June 21, 1994) (Vant Erve I) (ruling concerning entitlement issue).

From this point, both parties discussed settlement on the amount of damages to be awarded; petitioner filed a number of different life-care plans.⁽⁶⁾ During this time, respondent requested additional information to assist with development of their version of Christian's life-care plan. Part of this evaluation required a visit by respondent's life-care planner to Christian's home. Petitioners agreed to have Linda L. Cosby, a professional nurse and respondent's life-care planner, visit with Christian on January 23, 1997. Respondent's responsive life-care plan was filed on January 31, 1997, recommending a markedly different level of future care than that proposed by petitioners.

As a result of Ms. Cosby's visit, respondent applied for a subpoena for additional medical records relating to Christian.⁽⁷⁾ This application was opposed by petitioners as an attempt to reopen the issue of entitlement. The Special Master granted the subpoena on the basis that the information was necessary to assess the damages issue on February 20, 1997. Petitioners filed the requested documents on March 17 and April 23, 1997.⁽⁸⁾

Respondent filed a motion to reopen the issue of entitlement on June 2, 1997, based substantially on expert review of the medical information, including that recently supplied by petitioners.⁽⁹⁾ First, Dr. Charles R. Fitz, a neuroradiologist, reviewed the results of three post-petition MRI examinations; these examinations occurred in August 1992, April 1993, and January 1997.⁽¹⁰⁾ Dr. Fitz concluded: "It is impossible that this is a static disease from a vaccine injury. It is clearly a progressive dysmyelinating-metabolic disease. Nearly all such diseases are inherited." (Resp't's Entitlement Ex. F at 2.)

Second, Dr. Gale, respondent's expert neurologist, reviewed the transcript of the evidentiary hearing held on May 26, 1994, respondent's damages exhibits C through S, and the report of Dr. Fitz. (See Resp't's Entitlement Ex. G.) Dr. Gale states:

Dr. Mathisen's own records make two facts abundantly clear. First, Christian's clinical course since 1992 has been characterized by significant and continuous regression in his psychomotor development. This is supported by the observations documented in his academic and rehabilitation therapy records. Second, each of Christian's successive MRI studies has demonstrated increasing abnormality, predominately in his brain's myelinated, or white, matter. This point is corroborated by the interpretation of his neuroimages by Dr. Charles Fitz in his report dated May 28, 1997, and by the contemporaneous interpretations of the radiologists who initially reviewed the studies.

. . . Christian has a severe progressive and degenerative disease, almost certainly caused by a genetic inborn error of metabolism.

(Id. at 2-3.) A hearing on damages was held on June 10, 1997.

The Special Master denied respondent's motion to reopen the issue of entitlement on June 26, 1997. After noting that the decision whether to reopen the issue of entitlement was discretionary,⁽¹¹⁾ he applied a four-factor test to "reach the result that is most fair and equitable in light of those circumstances."⁽¹²⁾ Vant Erve v. Secretary of Health & Human Servs., No. 92-341V, slip op., at 10 (Ct. Fed. Cl. Spec. Master filed June 26, 1997) (Vant Erve II) (ruling on motion to reopen the issue of entitlement). Those four factors are (1) the nature of the proffered new evidence; (2) the prejudice to the parties; (3) the length of the delay; and (4) the reason for the delay.

The Special Master found that the evidence that came to light after the initial ruling on entitlement was important to the determination of entitlement, but that reopening would be unfairly prejudicial to petitioners, especially in light of the length of time between the determination of the issue and the motion to reopen. Moreover, the Special Master noted that, in arguing for reopening the issue of entitlement, respondent was relying on evidence that was readily available prior to the entitlement hearing. In other words, the proffered reason for the delay--that the evidence was not produced by petitioners--was the direct result of respondent's negligence; she could have asked for the documentation earlier. Respondent was not prejudiced, he noted, as the Fund had a substantial surplus.

On June 29, 1997, the Special Master directed an award to petitioners of over \$600,000 in cash and ordered respondent to set up an annuity to pay for Christian's care. See Vant Erve v. Secretary of Health & Human Servs., No. 92-341V (Ct. Fed. Cl. Spec. Master filed June 27, 1997) (decision on compensation). Respondent filed a motion for review of the Special Master's decision pursuant to RCFC app. J, Rule 23, on July 28, 1997, and filed a memorandum of objections on August 4, 1997. Respondent argues that the Special Master abused his discretion and violated the principle of fundamental fairness by refusing to consider relevant and reliable evidence pertaining to Christian's entitlement under the program before awarding compensation. Specifically, respondent alleges that the decision placed an improper burden on respondent to request documents that petitioners should have furnished without a special request.

Petitioners respond that the Special Master acted within his discretion in denying the respondent's motion to reopen because he properly considered the entire record, including the new evidence.⁽¹³⁾ Petitioners also argue that the attempt to admit the new evidence would be futile as it would not alter the outcome of the matter. They contend that at most the respondent has alleged that the injury is caused by an unknown metabolic disorder, which cannot be used to prove alternate causation. Petitioner also cites the undue delay of three years since the entitlement ruling as weighing in favor of refusing to reopen the issue.

DISCUSSION

A. Standard of Review

The court's power in vaccine cases under the Act is limited to a review of the record; the court may then:

(A) uphold the findings of fact and conclusions of law of the special master and sustain the special

master's decision,

(B) set aside any findings of fact or conclusion of law of the special master found to be arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law and issue its own findings of fact and conclusions of law, or

(C) remand the petition to the special master for further action in accordance with the court's direction.

42 U.S.C. § 300aa-12(e)(2) (1994). The Special Master's rulings regarding evidence are reviewed for abuse of discretion. See Munn v. Department of Health & Human Servs., 970 F.2d 863, 870 n.10 (Fed. Cir. 1992); Horner v. Secretary of Health & Human Servs., 35 Fed. Cl. 23, 26 (1996). Review for abuse of discretion entails a determination that "the trial court erred in interpreting the law or exercised its judgment on clearly erroneous findings of material fact, or its decision represents an irrational judgment in weighing the relevant factors" Chiu v. United States, 948 F.2d 711, 713 (Fed. Cir. 1991) (reviewing nonvaccine decision to award attorney's fees under the Equal Access to Justice Act)

The court agrees with the Special Master that his decision not to reopen the question of liability to consider the new exhibits offered by the respondent can only be reversed for an abuse of discretion. See 42 U.S.C. § 300aa-12(e)(2) (1994); Horner, 35 Fed. Cl. at 26. The decision was a difficult one under the circumstances, and the court is fully sympathetic with the Special Master and particularly with the petitioners and their child, who have suffered mightily. The integrity of the judicial process, nevertheless, requires that decisions on liability be based on established facts and in light of the applicable law. Neither the grievous circumstances of the petitioners nor the fact that the Vaccine Injury Compensation Trust Fund (Fund), see 26 U.S.C. § 9510, is well funded can overcome a fundamental problem of proof.

B. The Special Master's Four-Factor Test

The court begins with the circumstances in June 1997, when the Special Master was confronted with the respondent's motion to reopen. At that time the trial on liability was at an end, and the Special Master had issued a ruling on entitlement; a final decision had not yet been issued. The Special Master is correct, therefore, that the standards of Federal Rule of Civil Procedure 60(b)(2) for relief from a judgment did not directly apply.⁽¹⁴⁾ The record had theoretically closed on liability, however, and the flexible evidentiary standards applied in vaccine cases would not dictate automatic admission of the new materials. See 42 U.S.C. § 300aa-12(d)(3)(B); RCFC app. J, Rule 8. In this setting, the court agrees that the four-factor test identified by the Special Master is appropriate for deciding whether to reopen the record: (1) the nature of the proffered new evidence; (2) the prejudice to the parties; (3) the length of the delay; and (4) the reason for the delay. The court disagrees, however, with the way these factors were applied in this case.

1. Nature of the proffered evidence

The factors, in the court's view, are not of equal weight. The paramount test is the nature of the proffered new evidence. By this, the court understands the question to be the extent to which the new evidence is both relevant and affective of outcome.⁽¹⁵⁾ In other words, if the evidence is of marginal relevance and impact, the burden on the moving party increases dramatically with respect to the influence of the remaining factors. See Horner, 35 Fed. Cl. at 27 (noting that fundamental fairness required admission of highly probative evidence of vaccine record). On the other hand, if the evidence is highly relevant and clearly outcome determinative, the opposite follows--the importance of the remaining factors diminishes. Cf. Kaminski v. Secretary of Health & Human Servs., No. 91-652V, slip op., at 7-8 (Ct.

Fed. Cl. Oct. 27, 1997) (finding error in special master's refusal to reopen entitlement proceedings to hear probative, relevant testimony).⁽¹⁶⁾

The Special Master's analysis with respect to the first issue is brief. It is conceded that the recent expert reports "raise a very serious question about whether Christian's encephalopathy and seizure disorders . . . were caused instead by a 'metabolic disturbance.'" Vant Erve II, slip op., at 11. This puts a gentle face on Dr. Fitz's May 28, 1997, letter: "The findings are clearly one of a progressive leukodystrophy/dysmyelinating disease of some type. . . . It is impossible that this is a static disease from a vaccine injury. It is clearly a progressive dysmyelinating-metabolic disease. Nearly all such diseases are inherited." (Resp't's Entitlement Ex. F.) Moreover, the January 22, 1997, MRI revealed "extensive white matter signal changes" with atrophy. (Resp't's Damages Ex. C at 29.) As Dr. Gale's May 29, 1997, letter states, "each of Christian's successive MRI studies has demonstrated increasing abnormality." (Resp't's Entitlement Ex. G.) Even petitioners' expert, Dr. Mathisen, noted, in connection with Christian's April 1993 MRI scan, that the scan "was quite abnormal with evidence of both brain stem and cerebellar atrophy with relatively minimal changes involving the cerebral cortex." (Resp't's Damages Ex. C at 7.) The new evidence, if allowed and not rebutted, in other words, is conclusive that the liability decision is simply wrong.⁽¹⁷⁾ The Special Master erred in not giving adequate weight to the proffer.

2. Prejudice to the parties

The second factor is prejudice to the parties. While there is no bright-lines in applying this factor, it is clear that the opinion below takes into account irrelevant or immaterial facts. For example, overwhelming importance is attributed to the emotional "prejudice" that the petitioners will suffer if the liability decision is reversed: "during the period [of reconsideration] petitioners would, undoubtedly suffer great worry"; "if I were ultimately to change my ruling on entitlement, petitioners would suffer the special anguish of losing an award." Vant Erve II, slip op., at 11-12. These observations, while no doubt painfully true here, are simply not relevant. The same factor presumably could appear in connection with the sentiments of virtually any appellee.

Another form of prejudice relied upon is that petitioners "may have" expended resources on their son in reliance on an award beyond what they would have expended in the absence of the ruling on liability. This is speculative. Any expenditure is referred to as something that "could" have occurred. See id. at 12. There is no record support for an assumption that the petitioners incurred expenses in reliance on the preliminary ruling that they would not have otherwise incurred.

The opinion below also states that, if the new evidence ultimately is rejected, the petitioners will be prejudiced by the delay. While this observation is true, it merely states what was clear at the outset of the inquiry--the decision on liability might be correct. For this factor to be relevant, in other words, an assumption is required about the outcome. But that is the very reason for the first factor--what is the likelihood the new evidence will affect the result? If the new evidence is not likely to have an effect, it would be unnecessarily upsetting and prejudicial to delay the inevitable recovery. In any event, no symmetrical analysis would ever be made in connection with a petitioner's effort to reopen. The fact that the respondent would be deprived of an initial victory, in itself, would be irrelevant.

Particularly troubling, however, is the reliance, in this context, on the fact that the Fund has "grown to nearly \$1.1 billion" to demonstrate that there is no concomitant prejudice to the respondent. See Vant Erve II, slip op., at 13 & n.8. Such nongermane consideration blunts the first factor--the nature of the proffered evidence--which, in practical terms, can be said to enshrine the pursuit of truth. Although Congress understood that the ground rules that it established in terms of proof of liability were less

rigorous and would thus occasionally result in questionable compensation, each case is to be addressed on its own merits. The question has to be whether entitlement can be established in the case then being considered.

The real utility of the prejudice factor is in evaluating the practical consequences of reopening on the nonmoving party's ability to re-establish its case. For example, have witnesses become unavailable? Can certain tests not be duplicated? Has evidence been destroyed? No such prejudice to petitioners is offered here. In sum, the Special Master erred in his analysis of the prejudice factor, giving weight to factors irrelevant in the context of a request to reopen.

3. Length of & reason for the delay

The factor of the length of delay is problematic. If understood to value simple repose, then the length of time is relevant. But in the present circumstance, when the record was still open on the issue of damages and when a final decision had not been entered, the question of the length of time, by itself, is of diminished importance, except insofar as it relates to prejudice and fault. When there is no final judgment, the real inquiries should be whether the delay has prejudiced the nonmoving party and the identity of the party that caused the delay.

The Special Master finds the respondent negligent in not obtaining pre-entitlement hearing evidence and strongly rejects the suggestion that petitioner's chief witness, Dr. Mathisen, concealed the materials from respondent. There are problems with this analysis. First, the opinion below does not deal with the evidence that did not exist prior to the entitlement hearing. It is undoubtedly the case that the January 1997 MRI did not exist prior to the entitlement hearing, and, as stated above, it is apparently inconsistent with Dr. Mathisen's testimony that Christian's condition had stabilized. The Fitz and Gale letters of January 1997, are new, although admittedly based in large part on earlier records. Those were records, however, that were not reviewed by respondent's experts at the time of the entitlement hearing because they were not produced to the respondent.⁽¹⁸⁾ The December 13, 1994, letter from Dr. Mathisen is particularly relevant because he reported "progressive difficulties" with motor function and stated that "I suspect that there will be even further degeneration in his clinical status." (Resp't's Damages Ex. C at 4.)

Much evidence highly relevant to Christian's condition was generated after the initial exchange of documents in connection with the petition. It is also apparent that the respondent did not have those materials prior to the hearing on entitlement. The Special Master places the responsibility for that circumstance on the respondent. In the court's view, this was erroneous.

The three pieces of evidence at issue are the MRI scans taken in August 1992, April 1993, and January 1993. In addition, there are several letters from Dr. Mathisen, dated both before and after the entitlement hearing that the respondent did not receive until sometime in 1996. Finally, the respondent offers two new expert reports, referred to above, one from Dr. Fitz and the other from Dr. Gale. The reports make highly relevant findings on the basis of the material newly disclosed.

The MRI scans and reports are obviously probative on the issue of Christian's deterioration. Petitioners furnished respondent with the only then-existing MRI report when they filed their petition, the report of December 1991. Respondent was not furnished with the other two pre-entitlement-hearing MRI reports until sometime after the entitlement ruling. In this connection, the testimony of Dr. Mathisen is of particular concern. During his testimony in May 1994, he refers by date only to the December 1991 MRI report. As of that time, however, he had seen three MRI reports. Indeed the record is clear that he ordered them himself. (See Resp't's Damages Ex. C at 29-34.) He testified as follows:

Well, I think that if we had had any kind of perinatal process such as an injury in the newborn period, I think we probably within that time frame would have seen probably more changes. It is certainly possible that in children who have neurologic complications from any condition that the imaging may not show a whole lot. But on occasion we do see that on follow-up MRI scans that there is progressive white matter changes, or progressive brain atrophy if there is a specific perinatal event. And we did not see any of that.

(Entitlement Hr'g Tr. at 106 (emphasis added).) It turns out, however, that before this testimony, Dr. Mathisen had already written in connection with the April 1993 MRI scan that the "MRI scan was quite abnormal with evidence of both brain stem and cerebellar atrophy with relatively minimal changes involving the cerebral cortex. The findings were thought to be more compatible with an underlying genetic disorder involving the brain stem and cerebellar region." (Resp't's Damages Ex. C at 7.) On its face, the letter seems to contradict his later testimony. The letter, in turn, was based on his review of the imaging report from Children's Hospital, which reported the impression that "the findings of cerebellar atrophy as well as brain stem atrophy . . . [are] suggestive of either demyelination or gliosis in the cerebellar pontospinal region. The diagnostic considerations here would include Frederic's Ataxia, cerebellar pontospinal atrophy and ataxia telangiectasia. . . . The findings have been discussed with Dr. Jan Mathisen of neurology" (Resp't's Damages Ex. C at 32-33.)

Respondent should have had access to those MRI scans and reports and Dr. Mathisen's records in order to cross-examine him properly on his statement that there had been no atrophy. It was not negligent, given the impression created by Dr. Mathisen, for respondent to not ask for other MRI scans. At a minimum, the onus of the delay in production can be shared equally between the parties.

C. Burden of Production

Petitioners argue that the Act and the vaccine rules create a burden for the respondent to produce or, at a minimum, to ask for documents that may be missing from the initial submission.⁽¹⁹⁾ Respondent argues that the Act, as well as the policy behind the Act and the rules implementing the Act, place the onus of producing medical documents on the petitioners. It is unnecessary in this opinion to explore the scope of the petitioners' burden under the Act to update previously provided medical records and other relevant information sua sponte. The court merely holds that, under the circumstances, it was improper for the Special Master to penalize the respondent for not having requested these materials by refusing to admit evidence that is plainly relevant to key issues in this matter.

The Act creates certain evidentiary presumptions in favor of claimants, but it also places a burden on them to come forward with all relevant documents. See 42 U.S.C. § 300aa-11(c)(2) (1994). The court's vaccine rules are to the same effect. See RCFC app. J, Rule 2(e). In exchange, formal discovery is discouraged, and "the informal and cooperative exchange of information is the ordinary and preferred practice." Id. Rule 7(a). The Federal Rules of Civil Procedure and the rules of this court, in connection with discovery, place a responsibility on an answering party to supplement a prior response if "the party knows that the response though correct when made is no longer true." Fed. R. Civ. P. 26(e)(2); RCFC 26(e)(2).

Petitioners counter that under Vaccine Rule 4(a), the respondent has an obligation to request information that is missing from the petition. Rule 4 plainly contemplates that the respondent has the duty to ask for documentation that is apparently missing from the existing petitioner's submission. Here, respondent did in fact request additional records. The request was made in her Rule 4 report, filed September 8, 1992, after the August 1992 study performed by Dr. Mathisen, which apparently included a MRI scan ordered by Dr. Mathisen. In addition, Dr. Mathisen filed an affidavit on June 11, 1993, that specifically cited the

August 1992 study but neglected to mention a MRI scan in connection with that study or a subsequent April 30, 1993, study and MRI scan. While respondent did not specifically request these documents, it would be fundamentally unfair to deny the respondent the opportunity to argue from them. If the respondent had been on clearer notice of a gap in the records, perhaps it could be faulted for failing to more specifically ask for supplementation. Here, however, Dr. Mathisen's testimony creates the impression, albeit no doubt unintentionally, that he was speaking from materials previously submitted. It would turn the informal vaccine process on its head if--in circumstances such as those here, where information fundamental to the correct diagnosis came into existence, petitioners should have known that respondent was interested in the data, and the absence of those new materials was not known to respondent--the respondent had to specifically ask for supplementation of the petitioner's medical history or be barred from relying on it later. There is no support in the vaccine rules, in other words, for the observation below that "the primary reason for the delay in this case plainly seems to have been respondent's own negligence in failing to timely seek obvious relevant records." Vant Erve II, slip op., at 15. Respondent's perceived failure in this regard "weigh[ed] heavily against" it according to the Special Master. In this respect, the decision was also in error.

In sum, the decision not to reopen the question of liability was an abuse of discretion. The information offered was highly probative; the delay, while extensive was not prejudicial to petitioners; and the delay was not the fault of the respondent.

CONCLUSION

The Special Master's decision of June 27, 1997, to grant compensation is set aside in light of the erroneous decision of the previous day not to reopen the liability question to hear the new evidence. The case is remanded for further consideration in light of this ruling.

ERIC G. BRUGGINK

Judge

1. See 42 U.S.C. § 300aa-14(b)(2) (1994).
2. Encephalopathy is defined under the Act as "any significant acquired abnormality of, injury to, or impairment of function of the brain." 42 U.S.C. § 300aa-14(b)(3)(A) (1994). The Special Master noted below that the definition of "encephalopathy" provided by the Act is much broader than that normally used in the medical field. See Vant Erve v. Secretary of Health & Human Servs., No. 92-341V, slip op., at 12-13 (Ct. Fed. Cl. Spec. Master filed June 21, 1994) (Vant Erve I) (ruling concerning entitlement issue).
3. Specifically, respondent requested updated pediatric-clinic records, films and records from a June 1989 CT scan, and films and records from a December 1991 magnetic-resonance-imaging (MRI) scan. Respondent did not specify any other records.

4. During oral argument, petitioner asserted that this follow-up study necessarily involved another MRI scan, and thus respondent should have been aware that other MRI data was available.

5. Petitioners' attorney appeared by telephone at this evidentiary hearing. Dr. Mathisen testified by telephone.

6. Between February 1995 and January 1997, five different life-care plans were filed with the court: four by petitioners and one by respondent. Petitioners conceded during oral argument that respondent was not responsible for petitioners' delay in producing a final life-care plan. It is apparent that the different life-care plans were the result of Christian's worsening condition during that time period.

7. Respondent requested a subpoena duces tecum for:

any and all records pertaining to Christian Rhys Vant Erve, including, but not limited to, emergency department records, outpatient records, hand-written charts, nursing notes, doctor's notes, clinic records, imaging studies (including original films or copies thereof), laboratory tests or any other record pertaining to Christian Rhys Vant Erve, DOB 4/27/89.

(Resp't's Application for Subpoena filed Feb. 19, 1997, at 2.)

8. These documents consisted of school records, language skills reports, laboratory tests, and a physical-therapy assessment; no medical records from Dr. Mathisen or any other doctor were produced. The only prehearing data was a 1992 auditory brainstem test.

9. In addition, respondent requested that a damages hearing scheduled for June 10-11, 1997, be canceled pending the reopening of the issue of entitlement. The Special Master denied that request. A status conference was held on June 3, 1997, to discuss respondent's motion to reopen and motion to cancel the damages hearing. Petitioners opposed the motions orally at this meeting and waived the right to file a written opposition.

10. A total of four MRI scans were taken. The first was taken in December 1991, formed the basis of the petition, and was discussed in the 1994 evidentiary hearing. The second and third MRI scans were taken in August 1992 and April 1993 and were thus prehearing examinations. These were not produced to the respondent before the evidentiary hearing. The last MRI scan was performed in January 1997. All four scans were ordered by Dr. Mathisen.

11. There is no rule or statutory provision that governs respondent's request to reopen the issue of entitlement.

12. In applying the test, the Special Master analogized the respondent's motion to reopen the issue of entitlement to a motion for relief from judgment on account of newly discovered evidence. See Fed. R. Civ. P. 60(b)(2).

13. This proposition cannot be correct. In denying the motion to reopen, the Special Master considered the new evidence only for the purposes of determining whether the issue of entitlement should be reopened and not on the merits of either entitlement or compensation.

14. The Special Master cited two vaccine cases that were instructive in this scenario. In Koston v. Secretary of the Department of Health & Human Services, 23 Cl. Ct. 597 (1991), aff'd, 974 F.2d 157 (Fed. Cir. 1992), the court held that the Special Master acted within her discretion in refusing to allow

the respondent to amend the respondent's Rule 4 report to remove certain concessions made regarding causation. The court there analogized to Federal Rule of Civil Procedure 15(a) and used a four-factor test similar to the one used in this case. In Horner v. Secretary of Health & Human Services, 35 Fed. Cl. 23 (1996), the court held that fundamental fairness required that a hearing be reopened to introduce new evidence regarding the authenticity of the vaccine record. The court there noted that the authenticity of the vaccine record was of critical importance and thus tipped the scales with respect to fundamental fairness. Both cases are instructive as to application of the factors and reiterate the overriding importance of highly probative evidence.

15. The case law regarding Federal Rule of Civil Procedure 60(b) suggests the following factors for granting a motion for relief from judgment: "(1) the evidence was discovered after the summary judgment hearing [or trial]; (2) the moving party exercised due diligence to discover the evidence; (3) the evidence is material and not merely cumulative or impeaching; and (4) a new hearing considering the evidence would probably produce a different result." Alpern v. Utilicorp United, Inc., 84 F.3d 1525, 1535 (8th Cir. 1996). Two of the four factors involve the nature of the proffered evidence: materiality and effect on outcome.

16. In Kaminski v. Secretary of Health & Human Services, No. 91-624V, slip op. (Ct. Fed. Cl. Oct. 27, 1997), the special master refused to reopen an entitlement hearing to hear testimony from a witness whose existence the government discovered only during the entitlement hearing. That witness was going to testify as to her first-hand observations of the petitioner child's behavior during the relevant forty-eight-hour period. The court held that, because the special master relied on clinical testimony and was likely swayed by the failure to admit the new testimony, the exclusion of that testimony was error. While Kaminski highlights the importance of the nature of the proffered evidence, it is distinguishable from the instant case because there was no entitlement ruling at the time respondent moved to reopen the proceeding.

17. Petitioners contend for the first time in connection with the motion to reopen that the new evidence is futile in that it merely points to an ideopathic factor or condition, which would not be an adequate defense under the statute. Dr. Fitz, however, says that the condition is one of "a progressive demyelinating-metabolic disease," such as Leigh's disease, adrenoleucodystrophy, or Kearns-Sayre's disease. (See Resp't's Entitlement Ex. F.) The futility of the proffered evidence is part of the determination of the nature of the evidence. In Koston v. Secretary, Department of Health & Human Services, 974 F.2d 157 (1992), the Federal Circuit affirmed a determination by the U.S. Claims Court that the respondent's proffered alternative causation, Rett Syndrome, was not a "factor unrelated to the administration of the vaccine." The Act defines "factor unrelated to the administration of the vaccine" as "not includ[ing] any idiopathic, unexplained, unknown, hypothetical, or undocumentable cause, factor, injury, illness, or condition . . ." 42 U.S.C. §300aa-13(a)(2) (1994). On remand petitioners will have an opportunity to challenge Dr. Fitz's statement, as well as to argue an ideopathic factor.

18. These MRI scans, as well as other medical records, were not produced by petitioners prior to the evidentiary hearing. It is unclear at what point respondent came into possession of these documents. According to respondent, in their motion to reconsider filed June 2, 1997, she made numerous requests for documents. Petitioners delivered a "stack" of documents on July 12, 1996, which presumably included Dr. Mathisen's missing medical records. Dr. Mathisen's medical records were included in respondent's damages exhibit filing on May 2, 1997.

19. Petitioners argue that Wagner v. Secretary of the Department of Health and Human Services, 35 Fed. Cl. 134 (1997), places the burden on respondent for proving alternative causation. While this is technically true, petitioners misconstrue the applicability of Wagner to these facts.

In Wagner, the issue was whether petitioner should be required to prove that there were no alternative causes of petitioner's condition. The court held that the burden of proving alternative causation lay with the respondent, not petitioner, once the petitioner has proven his *prima facie* case. Here, respondent is not arguing that the burden of proving alternative causation be shifted to petitioners. Respondent seeks to reopen the issue of causation and thus entitlement in light of highly probative evidence that was not available prior to the entitlement decision. It is still respondent's responsibility to prove alternative causation. Thus Wagner is not dispositive of the issue here.