OFFICE OF SPECIAL MASTERS

No. 01-390V

(Filed: September 25, 2003)

KIENAN FREEMAN, by his Mother and Next Friend, REBEKAH SMOTHERS, Petitioner, v. SECRETARY OF HEALTH AND HUMAN SERVICES, Respondent.	**TO BE PUBLISHED**

Ronald Homer and Sylvia Chin-Caplan, Boston, Massachusetts, for petitioner.

Ann Donohue, Department of Justice, Washington, D.C., for respondent.

RULING CONCERNING "ENTITLEMENT" ISSUE

HASTINGS, *Special Master.*

This is an action in which the petitioner seeks an award under the National Vaccine Injury Compensation Program (see 42 U.S.C. § 300aa-10 *et seq*[1]), on account of an injury to her son, Kienan Freeman. For the reasons stated below, I conclude that petitioner is entitled to such an award, in an amount yet to be determined.

I

THE APPLICABLE STATUTORY SCHEME

Under the National Vaccine Injury Compensation Program (hereinafter the "Program"), compensation awards are made to individuals who have suffered injuries thought to be caused by

[1]The applicable statutory provisions defining the Program are found at 42 U.S.C. § 300aa-10 *et seq*. (2000 ed.). Hereinafter, for ease of citation, all "§" references will be to 42 U.S.C. (2000 ed.).

certain 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 an injury thereafter; and has received no previous award or settlement on account of the injury. Finally--and the key issue in most cases under the Program--the petitioner must also establish a causal link between the vaccination and the injury. One method by which the petitioner may establish this link is by demonstrating the occurrence of what has been described as a "Table Injury." That is, the statute provides for the creation of a "Vaccine Injury Table,"consisting of a list of specified types of injuries for each type of vaccination covered by the statute, along with a specified time period after vaccination in which such an injury must occur. The petitioner may show that the vaccine recipient suffered an injury of the type enumerated in the Vaccine Injury Table with respect to the vaccination in question, and that either the first symptom of the onset of that injury, or the first symptom of a "significant aggravation" of that injury, occurred within the required time period after the vaccination. 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).

Alternatively, if no injury falling within the Vaccine Injury Table can be shown, the petitioner may establish the required causal link by showing that the vaccine recipient's injury was "caused-in-fact" by the vaccination in question. § 300aa-13(a)(1)(A); § 300aa-11(c)(1)(C)(ii).

II

BACKGROUND FACTS

Kienan Freeman was born on March 21, 1998. The petitioner, Rebekah Smothers, is his mother. For the first 16 months of life, although he experienced a number of ear infections, Kienan seemed to develop normally and experience generally good health. (See generally Ex. 3.[2])

On July 30, 1999, at the age of 16 months, Kienan received a measles-mumps-rubella ("MMR") inoculation. (Ex. 3, p. 7.) Eight days later, on August 7, 1999, Kienan was taken to a hospital emergency room, after he was found to be exhibiting seemingly involuntary movements described as "twitching" and eye deviations. (Ex. 2, pp. 188, 191, 193.) At the hospital, Kienan was found to be in a "postictal" state–*i.e.*, the state after a seizure. (*Id*. at 191.) He was then observed to suffer an extended seizure in the emergency room, which finally subsided after he was administered anti-seizure medications. (*Id.* at 188, 191.) While some hospital records indicate that

[2]Petitioner filed exhibits numbered 1 through 10 with the petition, and additional consecutively-numbered exhibits on several occasions thereafter. Respondent filed exhibits A through K. "Ex." references will be to those exhibits. (I note that petitioner's Ex. 11 was accompanied by a number of medical articles, at Tabs A through J. I will refer these articles as "Ex. 11-A," "Ex. 11-B," etc.) "Tr." references will be to the pages of the transcript of the evidentiary hearing held on June 20, 2002.

the duration of Kienan's seizure episode was about 45 minutes (*e.g.*, Ex. 2 at 188), careful analysis of those records indicates that more likely his seizure episode lasted 60 to 75 minutes, or more. (See Tr. 54-57; Ex. 2, pp. 221-22.)

Kienan was kept in the hospital for two days, being discharged on August 9, 1999, with the diagnosis of "atypical febrile seizure." (Ex. 2, p. 188.) During the next several weeks, Kienan did not experience any seizures. However, on October 30, 1999, Kienan suffered another prolonged seizure, again prompting a two-day hospitalization. (Ex. 2, pp. 130-155.) Thereafter, Kienan began to suffer increasingly frequent seizures of short duration, without fever. He had seizures on December 19, 1999, and January 6, 2000 (Ex. 3, p. 10, entry for 1/6/00), and apparently also suffered a number of additional seizures during those months (Ex. 3, p. 10, entry for 1/31/00; Ex. 4, p. 6). By early February, he was experiencing several seizures per week. (Ex. 2, p. 12.)

In the weeks after Kienan's first seizure episode on August 7, 1999, according to his mother, his ability to speak seemed to regress. (Ex. 9, p. 3, para. 6.) By early 2000, as his seizures became frequent, concern about Kienan's development increased. In March of that year, Kienan was assessed by a multi-disciplinary team, and found to be significantly delayed in his development. (Ex. 6.) Since that time, Kienan has continued to suffer from seizures, and has proven to be significantly delayed in mental and other developmental abilities. No cause for his seizures and retardation has ever been definitively diagnosed.

III

ISSUE TO BE ADDRESSED

Petitioner argues that she is entitled to a Program award on Kienan's behalf, on the theory that Kienan's seizure disorder and mental retardation were "caused-in-fact" by his MMR vaccination of July 30, 1999.[3] I have determined that petitioner is entitled to an award pursuant to her theory of "causation-in-fact." My reasoning concerning that "causation-in-fact" issue will appear in the following section of this Ruling.

IV

"CAUSATION-IN-FACT" ISSUE

After careful consideration of the entire record in this case, I conclude that it is "more probable than not" that Kienan's MMR vaccination of July 30, 1999, "caused-in-fact" his subsequent seizure disorder and mental retardation. The shortest summary of my reasoning behind this conclusion is that I simply found the testimony of petitioner's expert, pediatric neurologist

[3]The petition in this case asserted that Kienan suffered an unspecified "Table Injury," but by the time of the hearing in this case, petitioner had abandoned any Table Injury theory, and argued only a "cause-in-fact" theory of the case.

Dr. Marcel Kinsbourne, slightly more persuasive than that of respondent's expert, pediatric neurologist Dr. Russell Snyder. A more detailed explanation will follow.

A. Applicable case law

In analyzing a contention of "causation" in fact under the Vaccine Act, the burden is on the petitioner to show that in fact the vaccination in question more likely than not caused the injury or death.[4] *See, e.g., Hines v. Secretary of HHS*, 940 F. 2d 1518, 1525 (Fed. Cir. 1991); *Carter v. Secretary of HHS*, 21 Cl. Ct. 651, 654 (1990); *Strother v. Secretary of HHS*, 21 Cl. Ct. 365, 369-70 (1990), *aff'd* 950 F. 2d 731 (Fed. Cir. 1991); *Shaw v. Secretary of HHS*, 18 Cl. Ct. 646, 650-51 (1989). Thus, the petitioner must supply "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." *Shaw*, 18 Cl. Ct. at 651; *Hasler v. United States*, 865 F. 2d 718, 724 (6th Cir. 1989). The petitioner need not show that the vaccination was the sole cause or even the predominant cause of the injury or condition, but must demonstrate that the vaccination was at least a "substantial factor" in causing the condition, and was a "but for" cause. *Shyface v. Secretary of HHS*, 165 F. 3d 1344, 1352 (Fed. Cir. 1999).

B. Summary of experts' opinions

Dr. Kinsbourne, in his initial written report (Ex. 11) and in his hearing testimony, indicated the view that Kienan's extended seizure on August 7, 1999, was caused by the measles portion of his MMR vaccination received eight days earlier. Dr. Kinsbourne opined that this initial, prolonged seizure damaged Kienan's brain, causing his ongoing seizure disorder, and that those recurring seizures, in turn, caused Kienan's retardation. Dr. Snyder, on the other hand, in his initial written report (Ex. A) and hearing testimony, opined that while the August 1999 seizure likely was caused by the MMR vaccination, that seizure had no lasting effect on Kienan. Dr. Snyder believes that Kienan's seizure disorder and retardation are likely due to some type of brain abnormality that predated his MMR immunization in question.

Although the question is a very close one, concerning which reasonable minds can differ, I find Dr. Kinsbourne's approach to be slightly more persuasive.

C. The seizure of August 7, 1999, was likely caused by the MMR vaccination

First, I find it very likely that Kienan's seizure of August 7, 1999, was caused by his MMR vaccination of July 30, 1999. I note that there is really no dispute on this point. Dr. Snyder acknowledged that the seizure episode of August 7 likely was caused by fever that, in turn, was likely

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[4]Petitioner has the burden of demonstrating the facts necessary for entitlement to an award by a "preponderance of the evidence." § 300aa-13(a)(1)(A). Under that standard, the existence of a fact must be shown to be "more probable than not." *In re Winship*, 397 U.S. 358, 371 (1970) (Harland, J., concurring).

caused by the MMR vaccination. (Tr. 90-91.) Further, as Dr. Kinsbourne explained, the seizure occurred eight days after Kienan's MMR vaccination, exactly when one would expect a seizure caused by an MMR vaccination. (Tr. 6.)

D. The seizure episode of August 7, 1999, likely caused Kienan's seizure disorder and retardation

In part C above, I conclude that Kienan's *MMR vaccination* was the likely cause of his *seizure episode* of August 7, 1999. Accordingly, the next question, and the key question in this case, becomes whether that initial *seizure episode*, in turn, caused Kienan's *ongoing seizure disorder and retardation*. This is a vastly more difficult question, but, in the final analysis, I found Dr. Kinsbourne's approach to be slightly more persuasive. A discussion of my reasons will follow.

1. Evidence supports an association between measles vaccination and neurologic disorders

The record in this case contains strong evidence indicating that neurologic disorders, in the form of both encephalopathy (brain disorder) and seizure disorder, have been found to be associated with both the measles virus in its natural, "*wild*" form, and with the measles *vaccine*. One item of evidence is Ex. 11-I, an article authored by certain officials of the Department of Health and Human Services, in fact the very officials who administer the Program for the Secretary of Health and Human Services. The article notes (p. 1) that encephalopathy serious enough to cause death or permanent nervous system impairment is known to be associated with infection by the *wild* measles virus. The article's authors then examined cases in which persons suffered encephalopathies without determined cause within 15 days after a measles *vaccination*. Observing that such encephalopathies most often occurred on the eighth or ninth day after vaccination, the authors concluded that this result "suggests that a causal relationship between measles vaccine and encephalopathy exists as a rare complication of measles immunization." (Ex. 11-I, p. 1.)

In addition, Dr. Kinsbourne stated that his review of the medical literature indicates that the literature supports the view that both the *wild* measles virus and the measles *vaccine* can cause encephalopathies, resulting in both seizures and retardation. (Tr. 11-12.) And Dr. Snyder also acknowledged both that the *wild* measles virus "has been known to cause encephalitis and seizure disorders," and that medical literature "has associated MMR *vaccination* with seizure disorders." (Tr. 90-91, emphasis added.)

2. Significant evidence supports the proposition that severe, extended febrile seizures are associated with a higher risk of subsequent seizure disorder

Next, I note that petitioner submitted a number of articles of medical literature supporting the proposition that a severe, extended febrile seizure is associated with a higher risk of subsequent seizure disorders and/or other neurologic abnormality. See Exhibits 11-A, 11-C, 11-D, 11-E, 11-G, and 11-J.

Exhibit 11-A, the Annegers article, concluded that children who suffer a febrile convulsion that is both prolonged and focal (as was Kienan's seizure of August 7, 1999) have a much higher risk than other children of developing subsequent partial unprovoked seizures (as Kienan did). Exhibit. 11-C, the article by French and colleagues, concluded that "there is a very strong relationship between complicated febrile seizures during early childhood or infancy and the later development of medial temporal lobe epilepsy." (Ex. 11-C, first page--"medial temporal lobe epilepsy" is a form of seizure disorder.) Exhibit 11-D, the article by Hauser, reviewed previous studies of persons who had experienced "status epilepticus"--a term that describes the extended seizure that Kienan suffered on August 7, 1999--and noted that such persons often go on to experience recurrent seizures, mental retardation, and other neurologic abnormalities. (*E.g.*, Ex. 11-D, p. 8.) The analysis indicated a particularly high risk for subsequent "epilepsy" (seizure disorder) among children who, like Kienan, suffer a "prolonged" febrile seizure. (*Id*. at p. 10.)

Exhibit 11-E, the Rocca article, also indicated that febrile seizures are a significant precursor of recurring complex partial seizures, a term which describes Kienan's ongoing seizures. (Ex. 11-E, especially p. 24; Tr. 13-14.) And in Ex. 11-G, the Van Esch article, the authors studied 57 children who (like Kienan) experienced febrile status epilepticus without any prior history of neurologic deficits or seizures. The authors concluded that febrile status epilepticus "may cause severe neurological sequelae in previously healthy children." (Ex. 11-G, p. 23.)

In sum, these articles constitute impressive support for the proposition that persons who suffer a severe, extended febrile seizure, as Kienan did, are at a substantially increased risk of subsequently experiencing seizure disorders or other neurologic deficits. To be sure, respondent filed a medical article that took a different approach. Exhibit C, an article by Maytal and Shinner, described a study of 44 children who suffered extended (more than 30 minutes) febrile seizures. Nine of the children had exhibited neurologic deficits prior to the extended febrile seizure episode. The study found that among the 35 children *without* prior neurologic problems, there was *no* increased risk of recurring seizures. This study, as Dr. Snyder pointed out, does constitute an item of evidence tending to cast doubt on the proposition that an extended febrile seizure may cause recurring seizures. However, as Dr. Kinsbourne pointed out, this study must be evaluated in the context of other studies. As Dr. Kinsbourne explained, one study that finds no association does not necessarily outweigh several other studies that do find an association. (Tr. 99-101.)

I further acknowledge that, as Dr. Snyder pointed out, even if one assumes that the above-described studies on the whole indicate an *association* between an extended febrile seizure and subsequent recurrent seizures, that does not necessarily mean that the one *caused* the other. It could be that the sole cause of the association is that an underlying neurologic deficit causes *both* the original extended febrile seizure and the subsequent recurring seizures. However, as Dr. Kinsbourne argued, based upon the evidence of association set forth above, *plus* the existence of a plausible scenario by which an extended seizure might cause a subsequent seizure disorder (see point 3, p. 7, below), a reasonable case can be made that in some instances an extended seizure can *cause* a subsequent seizure disorder. (See especially Tr. 29-32.)

3. Evidence of a mechanism by which an extended seizure could result in a seizure disorder

Two medical articles filed by petitioner offer support to Dr. Kinsbourne's theory that an extended seizure could cause a subsequent seizure disorder by disorganizing or otherwise damaging the brain's neurons. The articles discuss a specific part of the brain, the hippocampus, which is the part of the brain implicated in partial complex seizure disorders, such as the disorder from which Kienan suffers. The Sankar article, Ex. 11-F, documents a study of animal brains, in which the animals developed seizure disorders after a single extended seizure was induced. Those animals showed changes in the hippocampus. The Van Landingham article, Ex. 11-H, documents a study of human infants who suffered prolonged febrile seizures, and concluded that prolonged febrile seizures "can occasionally produce hippocampal injury." (Ex. 11-H, first page.)

I also note that my review of Dr. Snyder's testimony indicates that Dr. Snyder did not specifically indicate disagreement with Dr. Kinsbourne's theory that a single extended febrile seizure *can* cause permanent brain damage. Dr. Snyder said that would be an "unusual" occurrence (Tr. 47), implying that in some instances it could happen, though Dr. Snyder finds it unlikely that it happened in Kienan's case.

4. Evidence supports the proposition that an ongoing seizure disorder can result in mental retardation

The record also includes support for Dr. Kinsbourne's theory that an ongoing seizure disorder can result in mental retardation. Exhibit 11-J is an excerpt from a medical textbook which indicates, at pp. 923-924, that recurrent seizures can lead to brain damage. In addition, I note that Dr. Kinsbourne testified that recurring seizures can lead to mental retardation by damaging the brain. (Tr. 7-8, 44.) Dr. Snyder, in his testimony thereafter, did seem to disagree with this general point of Dr. Kinsbourne, asserting that–

> when a seizure causes deterioration, like someone with repetitive seizures, then losing some skills, it is most likely that there's an underlying cause for both. The seizures don't cause the deterioration. There's something causing both, deterioration and seizures.

(Tr. 49.) But Dr. Snyder did not *explain why* he disagreed with Dr. Kinsbourne on this issue, or why he seems to disagree with the neurology textbook excerpt (*i.e.*, Ex. 11-J) upon which Dr. Kinsbourne relies concerning this point. As to this particular point, then, the fact that Dr. Snyder did not explain his reasons for disagreeing with Dr. Kinsbourne, coupled with the fact that Dr. Kinsbourne offered evidence (Ex. 11-J) for his viewpoint while Dr. Snyder offered none for his, causes me to accept the view of Dr. Kinsbourne over that of Dr. Snyder concerning this point.

5. Cross-examination of Dr. Snyder

Another important point is that the credibility of Dr. Snyder's opinion concerning the ultimate causation issue in this case was damaged during his cross-examination by petitioner's counsel.[5] That is, concerning a number of arguments that Dr. Snyder offered in support of his opinion, he either acknowledged that he had misunderstood the medical records, or retreated to some degree from a previously-stated interpretation. This occurred as to three separate issues.

The first example concerns the length of Kienan's initial seizure episode on August 7, 1999. Dr. Snyder had indicated that he did not think that that seizure had been long enough or severe enough to damage Kienan's brain. (Tr. 47-49, 53.) He indicated, that based upon animal experimentation, it would take a seizure of 60 minutes or more to rearrange the brain neurons enough to cause irreversible changes. (Tr. 53-54.) And he relied upon several notations in the medical record indicating that Kienan's seizure on August 7 lasted about 45 minutes. (Tr. 54; Ex. A, p. 1.) However, Dr. Snyder was then shown additional medical records that showed that Kienan's seizure episode probably lasted at least 60 to 75 minutes. (Tr. 54-57.)

Next, Dr. Snyder acknowledged that an EEG (electroencephalograph) procedure performed on Kienan on August 9, 1999, indicated brain abnormality. (Tr. 59-60.) He explained, however, that such abnormality, rather than an indication that Kienan's brain had been permanently damaged by the August 7 seizure, might indicate merely that Kienan was in a "postictal" (*i.e.*, post-seizure) state, or that his brain function was being affected by anti-seizure medication. (Tr. 61.) On cross-examination, though, Dr. Snyder first seemed to acknowledge that a "postictal state" as an explanation for the EEG abnormality was unlikely, given that two days had elapsed since the August 7 seizure. (Tr. 62.) Then, when questioned closely about the specific anti-seizure medication that Kienan had in fact received, Dr. Snyder's answers seemed to indicate that a "medication effect" was also not a likely explanation for the EEG abnormality. (Tr. 62-64.) Thus, Dr. Snyder's two suggested explanations for Kienan's brain abnormality, as shown on the August 9 EEG, seem to have been discredited.

Third, Dr. Snyder had opined that Kienan likely had a neurologic problem *prior to* the MMR vaccination in question, in part because Kienan had an abnormally small head circumference (indicating a poorly growing brain) even before the vaccination. (Ex. A, p. 2; Tr. 47.) Dr. Snyder was under the impression that Kienan's head size was "consistently around the second percentile before and after the immunization." (Ex. A, p. 2; Tr. 64.) On cross-examination, however, Dr. Snyder acknowledged that Kienan's head size did not fall to the second percentile until *after* the vaccination in question, and that his head growth prior to the vaccination seemed steady, likely indicating a growing brain. (Tr. 64-72.)

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[5] I note that the cross-examination of Dr. Snyder by Ms. Chin-Caplan, while low-key and respectful in tone, was the finest example of cross-examination of an expert witness that I have ever witnessed while presiding over Vaccine Act cases over the past 14 years.

To be sure, I do not mean to suggest that Dr. Snyder was not being candid in his answers. I have found him to be both an honest and a knowledgeable witness. However, Dr. Snyder's retreats on all of these important points may indicate that his analysis of this particular case may have been somewhat hasty or not fully considered. In addition, some of the reasons offered by Dr. Snyder for his ultimate conclusion in this case have been discredited. This factor adds to my reasons for crediting the analysis of Dr. Kinsbourne over that of Dr. Snyder concerning the ultimate issue in this case.

6. Dr. Snyder's theory of preexisting neurologic disorder

In reaching his opinion concerning the causation issue in this case, Dr. Snyder seemed to rely heavily on his view that Kienan exhibited evidence of neurologic dysfunction *prior* to his MMR vaccination, in the form of (1) abnormally small head circumference and (2) the failure to walk by 16 months. However, this part of his theory was called into question at the hearing.

First, as to the head circumference issue, as explained above (p. 8, third example), Dr. Snyder ultimately acknowledged that Kienan's head size did not fall to the second percentile until *after* the vaccination in question, and that his head growth prior to the vaccination seemed steady, likely indicating a growing brain. (Tr. 64-72.) Further, Dr. Snyder did not refute the testimony of Dr. Kinsbourne (Tr. 10) that Kienan's head size prior to vaccination was within the range of normality.

Second, as to the walking issue, at the hearing Dr. Kinsbourne explained his view that the available records were ambiguous as to whether Kienan was walking or close to walking by age 16 months, and that even assuming that he was not yet walking at that point, his status was still within the range of normality. (Tr. 10.) And, for whatever reason, Dr. Snyder did not thereafter offer testimony to refute Dr. Kinsbourne concerning that point.

Accordingly, while the walking issue remains somewhat murky, I found that Dr. Snyder failed to make a persuasive case that there exists substantial evidence that Kienan was neurologically abnormal prior to the MMR vaccination in question. This factor, too, thus, adds to my reasons for crediting the analysis of Dr. Kinsbourne over that of Dr. Snyder in this case.

7. Additional analysis

As noted above, taking into account all of the evidence in the record before me, I conclude that it is at least slightly more likely than not that Kienan's initial seizure on August 7, 1999, caused his ongoing seizure disorder and retardation. In this regard, I credit Dr. Kinsbourne's theory that the initial seizure damaged Kienan's brain, causing the recurring partial complex seizures thereafter, and that these additional seizures, in turn, further damaged his brain, causing the mental retardation. As explained above at parts 1, 2, 3, and 4 of Section IV(D) of this Ruling, pp. 5-7, there exists in the record here significant evidence supporting all of the essential subparts of Dr. Kinsbourne's theory. That is, evidence supports an association between the measles vaccine and neurologic disorders

(point 1); an association between extended febrile seizures and an elevated risk of recurrent seizures thereafter (point 2); a mechanism by which an extended febrile seizure could result in recurring seizures (point 3); and the proposition that recurring seizures can cause mental retardation by gradually damaging the brain (point 4). That evidence gives credence to Dr. Kinsbourne's ultimate conclusion with respect to Kienan, which puts together those four points.

To be sure, Dr. Snyder presented a reasonable argument with considerable appeal. As previously noted, the "causation" issue in this case is a very close question. Further, I acknowledge that Dr. Snyder is, like Dr. Kinsbourne, highly qualified to opine concerning this causation issue, and I have no reason to doubt that Dr. Snyder was giving me his honest, sincere view of the case. I have very carefully considered his testimony. However, as to each of the points upon which Dr. Snyder relied to support his view of the case, either that point was undermined during the cross-examination of Dr. Snyder, or I found the counter-arguments of Dr. Kinsbourne to be more persuasive. For example, as previously explained (points 5 and 6), Dr. Snyder on cross-examination was forced either to abandon or retreat from several of the premises upon which he originally based his own ultimate conclusion. Moreover, Dr. Snyder failed to persuasively refute any of the four basic subpoints upon which Dr. Kinsbourne based his ultimate conclusion--*i.e.*, that evidence supports an association between the measles vaccine and neurologic disorders; evidence supports an association between extended febrile seizures and an elevated risk of recurrent seizures thereafter; evidence supports a mechanism by which an extended febrile seizure could result in recurring seizures; and evidence supports the proposition that recurring seizures can cause mental retardation by gradually damaging the brain. Dr. Snyder certainly expressed disagreement with Dr. Kinsbourne as to some of these points, but did not point to persuasive evidence negating any of the four points.

I also note that it certainly seems possible that some of the four points of Dr. Kinsbourne described above may be scientifically controversial. I have not studied scientific materials outside the record of this case fully to test the validity of these points. Dr. Snyder may possibly have good reasons for doubting the validity of some of the points. But the *record of this case*, in my view, preponderates in favor of Dr. Kinsbourne's view on each of the four points, and in favor of the proposition that the seizure episode of August 7, 1999, likely caused Kienan's subsequent seizure disorder and retardation.[6]

Accordingly, although the issue is an exceedingly difficult one, for all the reasons set forth above, I conclude that it is at least slightly more probable than not that the seizure episode of August 7, 1999, caused Kienan's subsequent seizure disorder and retardation.

E. Overall conclusion concerning "causation-in-fact" issue

In part C of this Section IV, I concluded that Kienan's seizure of August 7, 1999, likely was caused by his MMR vaccination of July 30, 1999. In part D, I then concluded that the seizure of

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[6]I also note that in his second written report, Ex. 18, Dr. Kinsbourne supplied reasonable and persuasive answers to the two questions posed by my order of May 16, 2003.

August 7, in turn, was likely the cause of Kienan's subsequent seizure disorder and retardation. Putting those two factual conclusions together, I find as fact that Kienan's seizure disorder and retardation likely were the result of his MMR vaccination of July 30, 1999.[7]

V

FURTHER PROCEEDINGS

For the reasons stated above, I find that petitioner is entitled to a Program award on Kienan's behalf. Thus, petitioner's counsel may initiate efforts toward establishing the appropriate *amount* of the award. I will soon schedule a status conference to discuss that topic.

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George L. Hastings, Jr.
Special Master

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[7]It was noted at the hearing that Kienan's neurologic disorder has features that might cause it to be labeled as "atypical autism," a condition within the category of "autistic spectrum disorder." (Tr. 103-108.) I note, however, that even assuming that Kienan's disorder is correctly classified within the "atypical autism" category, that is essentially irrelevant to my ruling concerning the entitlement issue in this case. As Dr. Kinsbourne explained, Kienan's autistic-type features seem to be a result of the brain damage that caused his severe mental retardation. (Tr. 9, 21-22.) As Dr. Kinsbourne further explained, brain damage is one of the many possible causes of autism. (Tr. 108.) Thus, I cannot see why the fact that Kienan's disorder may fall within the autism spectrum has any substantial relevance to the question of what caused Kienan's seizure disorder and mental retardation.

Accordingly, I also note that, as far as I can see, the outcome of this case has no significant relevance to the many pending cases before me in which it is asserted that a MMR vaccination caused the vaccinee's autism disorder. As far as I am aware, none of those cases involves a prolonged seizure happening a week or so after vaccination. Therefore, I do not perceive that the petitioner's theory of causation in this case would be of relevance to those cases.

Further, I note that my conclusion that Kienan's neurologic disorder probably was caused by his MMR inoculation should not be interpreted as a conclusion that the MMR inoculation is a particularly dangerous vaccination. To the contrary, given the huge number of MMR inoculations that have been administered world-wide and the very small number of seizures or neurologic disorders reported after such inoculations, it is clear that any risk of neurologic injury from such inoculations is an extremely small one, confined to very rare instances. It remains clear that MMR vaccination is generally a very safe procedure, and that the risks resulting from *failure to receive* such vaccinations far exceed any very slight risk involved in *receiving* them.