

OFFICE OF SPECIAL MASTERS

No. 95-728V

(Filed: June 14, 1999)

CAROLINE I. LEWIS, a minor, by *
VICTORIA M. LEWIS, her mother and *
guardian, *

Petitioner, * **TO BE PUBLISHED**

v. *

SECRETARY OF HEALTH AND *
HUMAN SERVICES, *

Respondent. *

J. Bradley Horn, Vienna, Virginia, for petitioner.

Althea Davis, Department of Justice, Washington, D.C., for respondent.

DECISION

HASTINGS, Special Master.

This is an action seeking an award under the National Vaccine Injury Compensation Program⁽¹⁾ (hereinafter "the Program) on account of an injury to the petitioner's daughter, Caroline I. Lewis. For the reasons stated below, I conclude that petitioner is not entitled to such an award.

I

BACKGROUND FACTS AND PROCEDURAL HISTORY

Caroline I. Lewis, daughter of the petitioner, Victoria M. Lewis, was born several weeks prematurely on July 3, 1992. As a newborn, she had numerous complications, including breathing difficulties and an abnormal brain ultrasound examination, and was kept hospitalized until August 1, 1992. For the next several months, Caroline seemed to be generally healthy, and received DPT (diphtheria, pertussis, tetanus) vaccinations on September 17 and November 5, 1992.

On December 17, 1992, Caroline was taken to a hospital emergency room, where her mother reported that the infant had been exhibiting unusual arm and leg movements lasting about five minutes, during which period she also seemed unresponsive. Caroline was diagnosed to be suffering from seizures, and was admitted to the hospital. During that hospitalization, Caroline's mother reported to physicians that Caroline had experienced unusual body movements on several occasions prior to December 17. Since that hospitalization, Caroline has continued to experience seizures, and has proved to have a serious, permanent neurologic abnormality, the cause of which has never been conclusively determined.

On November 3, 1995, the petitioners filed this Program proceeding on Caroline's behalf, contending that Caroline's neurologic condition was caused by her DPT vaccination of November 5, 1992. An initial evidentiary hearing was held on September 30, 1997, at which hearing I heard the testimony of the petitioner. The hearing focused upon the issue of exactly when Caroline exhibited the first of the unusual body movements that she experienced in the weeks prior to the dramatic seizure episode of December 17, 1992. At the conclusion of that hearing, I made an oral ruling on that contested issue. I found it probable that the first of such unusual movements occurred about four days after the DPT vaccination of November 5, 1992. (See transcript of the 9-30-97 hearing, pp. 75-83, especially p. 83.) At that hearing, Caroline's mother also described certain symptoms that Caroline experienced within the first day after her DPT inoculation on November 5, 1992, including listlessness and paleness.

A second evidentiary hearing was held on April 28, 1999, at which hearing was taken the testimony of the two expert witnesses, to be discussed below.

II

STATUTORY BACKGROUND

Under the Program, compensation awards are made to individuals who have suffered injuries after receiving certain vaccines listed in the statute. There are two separate means of establishing entitlement to compensation. First, if an injury specified in the "Vaccine Injury Table," originally established by statute at § 300aa-14(a) and since modified administratively (as will be discussed *infra*), occurred within the time period from vaccination prescribed in that Table, then that injury may be *presumed* to qualify for compensation. § 300aa-13(a)(1)(A); § 300aa-11(c)(1)(C)(i); § 300aa-14(a). If a person qualifies under this presumption, he or she is said to have suffered a "Table Injury." Alternatively, compensation may also be awarded for injuries not listed in the Table, but entitlement in such cases is dependent upon proof that the vaccine *actually caused* the injury. § 300aa-13(a)(1); § 300aa-11(c)(1)(C)(ii).

One of the vaccinations covered under the Program is the "DPT" vaccination, a vaccination against the three separate diseases of diphtheria, pertussis, and tetanus. The statute contains a version of the Vaccine Injury Table that applied to DPT vaccinations administered prior to the enactment of the Program and for several years after that enactment. However, the Vaccine Injury Table was administratively modified with respect to Program petitions, such as this one, that were filed after March 10, 1995. See 60 Fed. Reg. 7678 (1995); *O'Connell v. Shalala*, 79 F. 3d 170 (1st Cir. 1996). That modified Table significantly altered the "Table Injury" categories with respect to DPT vaccinations. See 42 C.F.R. § 100.3(a)(I).⁽²⁾ In this case, the petition originally alleged that Caroline Lewis suffered the Table Injuries of "encephalopathy" and "seizure disorder." By the time of the hearing in this case, however, petitioner acknowledged that under the modified Table applicable to this case,⁽³⁾ (1) "seizure disorder" was no longer a Table Injury for the DPT vaccination, and (2) the modified "encephalopathy" Table Injury is also not applicable to Caroline's case.

Therefore, the dispute to be resolved here concerns only whether petitioner has demonstrated that it is "more probable than not"⁽⁴⁾ that Caroline's neurological disorder was *actually caused* by her DPT vaccination administered on November 5, 1992.

III

RESOLUTION OF THIS CASE

A. Summary of parties' positions

Petitioner relies chiefly upon the testimony and documentary evidence supplied by her medical expert, Dr. Mark R. Geier, a physician specializing in medical genetics. Dr. Geier supplied petitioner's Ex. 13

(filed September 23, 1998), which consists of his written analysis of this case plus copies of a number of items of medical literature. He then testified orally at the evidentiary hearing held on April 28, 1999.

Dr. Geier testified that he has intensively studied the available evidence concerning the issue of whether the whole-cell pertussis vaccine,⁽⁵⁾ which was part of the DPT inoculation that Caroline Lewis received, causes chronic or permanent neurologic injury. He stated the opinion that that vaccine can and does cause such chronic injuries on rare occasions, and that it did cause such an injury to Caroline. Dr. Geier explained that the medical literature relevant to that topic spans the many decades during which the whole-cell pertussis vaccine has been in use. He listed the titles of many of these articles of medical literature at Tab B to Ex. 13; he included copies of a number of the articles themselves at Tabs C through AA of that exhibit. Dr. Geier explained, as he had in testimony before me in several previous Program cases, that based upon this medical literature he has reached the following conclusion: When a neurologically sound individual receives the whole-cell pertussis vaccine, manifests a significant neurologic symptom within seven days thereafter, goes on to develop a chronic neurologic abnormality, and a thorough medical work-up fails to identify a cause for the chronic abnormality, it is more probable than not that the chronic abnormality was caused by the pertussis vaccine.

Dr. Geier testified, in addition, that he believes that the case of Caroline Lewis fits within his general causation theory. He opined that the listlessness and paleness symptoms that Caroline displayed on the day of the inoculation were indicative of neurologic damage. He stated that the unusual movements that Caroline occasionally displayed over the following few weeks, the first of which likely took place about four days after the inoculation, likely constituted seizures. Dr. Geier explained that the occurrence of this episode, which he views as a seizure, constitutes the significant neurological event, occurring within seven days from the date of the vaccination, that enables him to opine that Caroline's chronic neurologic dysfunction was vaccine-caused.

Dr. Geier also made special mention of a document to which I will refer as the "1994 IOM Report." (A copy of that report appears at Tab G of petitioner's Ex. 13, which was filed on September 23, 1998.) That report was issued by a committee of physicians selected by the Institute of Medicine ("IOM"), the medical arm of the National Academy of Sciences. Dr. Geier pointed to that report's conclusion that the available medical evidence is "consistent with" the existence of a causal relationship between the pertussis vaccine and chronic neurologic dysfunction, in children who experience a "serious acute neurologic illness" within seven days after pertussis vaccination. (See Ex. 13 Tab G, p. 195.) Dr. Geier argued that by this statement the IOM committee indicated the belief that when a child receives pertussis vaccine, experiences a "serious acute neurologic illness" within seven days thereafter, goes on to experience chronic neurologic dysfunction, and no other cause for the dysfunction is found, it is probable (though not certain) that the chronic dysfunction was caused by the vaccine. Dr. Geier opined that Caroline's case fits within this category of cases, and, thus, that the 1994 IOM Report should be viewed as supportive of a conclusion that Caroline's chronic neurologic dysfunction was vaccine-caused.

Respondent, on the other hand, relied chiefly upon Dr. John T. Sladky, who filed a written report on January 19, 1999, and also testified at the hearing on April 28, 1999. Dr. Sladky, a pediatric neurologist,

opined that it is incorrect to conclude that Caroline's chronic neurologic condition was vaccine-caused. First, he noted that Caroline's prematurity, severe neonatal difficulties, and history of apneic events put her at considerable risk to later manifest serious neurologic problems, even in the absence of any subsequent injury or neurologic insult.

More importantly, Dr. Sladky explained that while in some circumstances he could opine that an individual's chronic neurologic condition was likely vaccine-caused, the particular facts of Caroline's medical history make it seem quite unlikely that her condition was caused by her pertussis vaccination. He disagrees with Dr. Geier's view that Caroline's "spells" of unusual movements during the six weeks following the vaccination can reasonably be deemed seizures; Dr. Sladky finds that there is insufficient data to reasonably conclude whether they were seizures or not. Moreover, Dr. Sladky stressed that if a pertussis vaccination were in fact to injure a child's brain severely enough to cause the type of chronic dysfunction from which Caroline has suffered, he would expect to see very *significant and dramatic* symptoms of brain injury during the first several days post-vaccination, not merely the first of a widely-spaced series of brief, unrecognized seizures, as Dr. Geier views Caroline's case.

Finally, Dr. Sladky also took issue with Dr. Geier's argument that the 1994 IOM Report supports a finding of vaccine-causation of Caroline's condition. Among other points, Dr. Sladky opined that Caroline did *not* suffer a "serious acute neurologic illness," of the type contemplated by the IOM committee, within seven days of her DPT vaccination.

B. Analysis of this case

I conclude that the petitioner has failed to show that it is "more probable than not" that Caroline Lewis has suffered any injury caused by her DPT vaccination. The short summary of my analysis is that I simply found the testimony of Dr. Sladky to be substantially more persuasive than that of Dr. Geier. There are a number of reasons for this conclusion. I will summarize the three key points below.

1. It is not clear that Caroline experienced a seizure within seven days of her vaccination

First, as to the preliminary question of whether Caroline's series of unusual movements prior to her grand mal seizure on December 17, 1992, constituted seizures, Dr. Sladky has the overwhelming advantage that he is a superbly-qualified pediatric neurologist, while Dr. Geier is neither a pediatrician nor a neurologist. Dr. Sladky is far more qualified to state an opinion on this point, and I found him to be a candid witness as well. Accordingly, I am persuaded by Dr. Sladky that it is not possible to reasonably conclude that Caroline's unusual movements, including the one that may have taken place

about four days after her vaccination, constituted seizure activity. This conclusion itself effectively renders the rest of Dr. Geier's theory useless to petitioner in this case. That is, as I have understood Dr. Geier to explain in this and prior Program cases, under his own theory he can attribute a chronic neurologic condition to a pertussis vaccination *only* if the vaccinee suffers manifests a *significant neurologic symptom*, such as a seizure, within the seven-day post-vaccination period. Thus, in this case, since I cannot find it probable that Caroline suffered even a single seizure within the week post-vaccination, then Dr. Geier's basic theory, even if adopted, would not support a "causation" conclusion in Caroline's case.⁽⁶⁾

2. The 1994 IOM Report does not support a "causation"

conclusion in this case

Second, I found that Dr. Sladky effectively refuted Dr. Geier's argument that the 1994 IOM Report supports a causation finding in Caroline's case. As noted above, Dr. Geier placed special reliance upon the 1994 IOM Report's conclusion that the available medical evidence is "consistent with" a causal relationship between the pertussis vaccine and chronic neurologic dysfunction, in children who experience a "serious acute neurologic illness" within seven days after pertussis vaccination. (See Ex. 13, Tab G, p. 195.) Dr. Geier argued that by this statement the IOM committee indicated the belief that when a child receives pertussis vaccine, experiences a "serious acute neurologic illness" within seven days thereafter, goes on to experience chronic neurologic dysfunction, and no other cause for the dysfunction is found, it is probable (though not certain) that the chronic dysfunction was caused by the vaccine. Dr. Geier opined that Caroline's case fits within this category of cases, and, thus, that the 1994 IOM Report should be viewed as supportive of a conclusion that Caroline's chronic neurologic dysfunction was vaccine-caused.

Dr. Sladky, however, pointed out a glaring deficiency in this theory as to *Caroline's* case--*i.e.*, the fact that Caroline did *not* experience a "serious acute neurologic illness," of the type contemplated by the IOM committee, within the seven-day period following her DPT vaccination. That is, even *assuming* that Caroline did experience the first of her unusual jerking movements about four days post-vaccination, and also that such movement constituted a seizure, it seems clear to me that the 1994 IOM committee would *not* have considered that single subtle seizure to constitute a "serious acute neurologic illness," as that committee utilized that term. To explain my conclusion, I must briefly describe the studies that led to the 1994 IOM Report, and that report itself.

The 1994 IOM Report is reproduced at Ex. 13, Tab G. As explained therein, that Report was a follow-up to a report issued in 1991 by another IOM committee. The 1991 IOM committee studied all of the available evidence relevant to the issue of whether the pertussis vaccine causes neurologic injury, including a significant British study released in 1981, known as the National Childhood Encephalopathy Study (hereinafter "NCES").

The NCES researchers identified children in Great Britain between the ages of two and 35 months who were admitted to a hospital between 1976 and 1979 with one of the following diagnoses:

1. acute or subacute encephalitis, encephalomyelitis, and encephalopathy * * *;
2. unexplained loss of consciousness;
3. Reye syndrome;
4. convulsions with a total duration of more than half an hour, or followed by coma lasting 2 hours or more, or followed by paralysis or other neurologic signs not previously present and lasting 24 hours or more; or
5. infantile spasms (West syndrome).

(Ex. 13, Tab G, p. 186.) Children who were identified as having been admitted to hospitals with such diagnoses thus became the "case children" in the study. The NCES researchers then looked at the vaccination histories of the case children, in order to determine which of them had received a DPT vaccination within the seven-day period prior to the onset of the symptoms that led to the hospital admission. (*Id.* at 188.) The researchers determined that the frequency of neurologic incidents, of the type specified in the quotation above, was significantly higher, in children who had received DPT vaccinations within the previous seven days, than would have been expected by chance alone. (*Id.*) This determination of the original NCES, thus, led the 1991 IOM committee to conclude that the medical evidence is "consistent with a causal relation between DPT vaccine and *acute* encephalopathy." *Id.* at 183, emphasis added. ("Encephalopathy" indicates brain dysfunction; "acute" indicates a *severe, short-term* incident as opposed to a "chronic" condition.) It is also noteworthy that the 1991 IOM committee concluded that the available evidence was *insufficient* upon which to base a conclusion as to whether the pertussis vaccine causes *chronic* or *permanent* neurologic injury. (*Id.* at 181.)

In 1993 came the publication of a follow-up study to the NCES, which looked at the "case children" from the original NCES, ten years later. That follow-up study showed that the case children, *including* those children whose original hospital admissions occurred within seven days after DPT vaccination, were significantly more likely than non-case children to suffer from *chronic* neurologic dysfunction. The 1994 IOM committee then reviewed the 1993 NCES follow-up study, in conjunction with the evidence that the 1991 IOM committee had studied. The 1994 IOM committee *put together* the conclusion that

the 1991 IOM committee had drawn from the original NCES--*i.e.*, that the DPT vaccine can cause *acute* neurologic dysfunction--with the results of the 1993 NCES follow-up study --*i.e.*, that persons who suffer severe *acute* neurologic incidents as small children are at a considerable increased risk for *chronic* neurologic dysfunction. Putting these two results together, the 1994 IOM committee reached the conclusion here in question, *i.e.*, that the medical evidence--

is consistent with a causal relation between DPT and the forms of chronic nervous system dysfunction described in the NCES in those children who experience a serious acute neurologic illness within 7 days after receiving DPT vaccine.

Ex. 13, Tab G, p. 195 (emphasis in original).

The critical part of the quotation above, then, is the phrase "in those children who experience a serious acute neurologic illness within 7 days after receiving DPT vaccine." What did the 1994 IOM Committee mean by those words, "serious acute neurologic illness"? Reading the 1994 IOM Report in its entirety, in conjunction with the 1991 IOM Report, I find that it is clear what the 1994 committee meant. In my view, the committee was referring to children who suffered neurologic events that *would have qualified then as "case children"* under the original NCES, and who suffered such events within seven days after receiving DPT vaccinations. In other words, children who experienced neurologic events of the type specified in the quotation at pp. 6-7, above, and experienced such events within seven days after receiving DPT vaccine.

Does Caroline Lewis, then, fall within the category of children described by the 1994 IOM committee's phrase in question? She does not. Within seven days of her DPT vaccination in question, Caroline experienced, at most, only a single, subtle seizure, unrecognized as such at the time. While a seizure episode *could* constitute a "serious acute neurologic illness" of the type envisioned by the 1994 IOM committee, such an episode would have to fall within the description of point number 4 in the list quoted at pp. 6-7 above--*i.e.*, a seizure episode would qualify only if it lasted for more than half an hour or was followed immediately by coma, paralysis, or other long-lasting neurologic signs. This was clearly *not* the case with respect to Caroline. Her initial subtle seizures--if that is what they were--certainly did not last for half an hour, nor were they followed by any significant neurologic signs until several weeks later, on December 17, 1992. [\(7\)](#)

In sum, because Caroline does *not* fall within the category described in the 1994 IOM Report's conclusion--*i.e.*, "children who experience a serious acute neurologic illness within 7 days after receiving DPT vaccine"--that report's conclusion is of no assistance in demonstrating that Caroline has a vaccine-caused condition.

3. The evidence in the record before me does not support Dr. Geier's

own "causation" theory

I recognize, of course, that, as mentioned above, Dr. Geier does not rely solely upon the 1994 IOM Report, the NCES, and the 1993 NCES follow-up study, as support for his conclusion that the chronic neurologic dysfunction of Caroline Lewis was vaccine-caused. Rather, Dr. Geier testified that he has intensively studied a wide range of evidence concerning the issue of whether the pertussis vaccine causes chronic neurologic injury. Dr. Geier listed the titles of many articles of medical literature at Tab B to Ex. 13; he included copies of a number of the articles themselves at Tabs C through AA of that exhibit. He explained, as he has in testimony before me in several previous Program cases, that based upon the medical literature he has reached the following conclusion: When a neurologically sound individual receives the whole-cell pertussis vaccine, manifests a significant neurologic symptom within seven days thereafter, goes on to develop a chronic neurologic abnormality, and a thorough medical work-up fails to identify a cause for the chronic abnormality, it is reasonable to conclude that it is "more probable than not" that the chronic abnormality was caused by the vaccine.

Dr. Geier testified further that he believes that the case of Caroline Lewis fits within his general causation theory. He opined that the listlessness and paleness symptoms that Caroline displayed on the day of the inoculation were indicative of neurologic damage. He stated that the unusual movements that Caroline occasionally displayed over the following few weeks, the first of which likely took place about four days after the inoculation, likely constituted seizures. Dr. Geier explained that the occurrence of this episode about four days post-inoculation, which he views as a seizure, constitutes the significant neurologic event, occurring within seven days from the date of the vaccination, that enables him to opine that Caroline's chronic neurologic dysfunction was vaccine-caused.

As explained above (p. 5) even if I *could* accept as likely Dr. Geier's general theory of causation, it would still not benefit Caroline Lewis, since petitioner has failed to demonstrate that the unusual movement that Caroline first exhibited about four days post-vaccination was likely a seizure. But more importantly, I also conclude that Dr. Geier in this case has *failed to persuade me that his general causation theory is valid*.

First, Dr. Geier in this case spent relatively little time discussing any specific medical literature beyond the 1991 and 1994 IOM Reports, the original NCES, and the 1993 NCES follow-up study. To be sure, as noted above, Dr. Geier has pointed in this case to a number of medical articles that provide at least some support for the view that the pertussis vaccination can cause chronic neurologic injury. I have read the articles that he supplied as Tabs C through AA to his Ex. 13 in this case, as well as many of the articles to which he has cited at Tab B of the exhibit. They certainly provide strong reason to *suspect* that the pertussis vaccine can cause serious chronic neurologic injury. But, on the other hand, this point is tremendously controversial. A number of medical studies have found no link between pertussis vaccination and serious neurologic injury. See, *e.g.*, the articles by *Gale et al.*, *Griffin et al.*, and *Walker et al.* cited at Ex. 13, Tab G, p. 188. Even the NCES itself, the study that has provided the best evidence

to date for the theory that the pertussis vaccine causes serious neurologic injury, certainly provides evidence that is less than overwhelming. Interpreted even in the light most favorable to the theory of vaccine-causation, the NCES indicates that causation of serious neurologic injury by pertussis vaccine is *at most an extremely rare event*. (See, *e.g.*, Ex. 13, Tab G, bottom of p. 188.)

Moreover, even if one accepts the conclusion that the pertussis vaccine does on rare occasions cause serious, permanent neurologic injury, the question remains how one can point to a *particular* case and say that it is "more probable than not" that such person's chronic neurologic dysfunction was vaccine-caused. In my view, Dr. Geier in this and other cases has simply failed to demonstrate that sufficient evidence exists to support his general causation theory. He has failed to point to *particular* studies, beyond the NCES, and to explain *how* they support his theory.

In addition, Dr. Sladky pointed out a substantial problem with Dr. Geier's general theory. That is, Dr. Geier, as explained above, would accept vaccine-causation based upon the occurrence of one of a wide range of neurologic illnesses or symptoms within seven days after vaccination, including the occurrence of a single, subtle seizure that is recognized as a seizure only weeks later. Dr. Sladky, however, testified that he can find the pertussis vaccine to be capable of causing chronic neurologic injury *only* in a situation in which there occurred some type of *significant, dramatic episode* of neurologic injury, such as a coma or a very lengthy seizure, within the first few days (seven at most) after the vaccination. (See, *e.g.*, Tr. 4-28-99 at pp. 164-169, 201.) Dr. Sladky explained that he cannot understand how the pertussis vaccine could injure the brain in such a fashion that the only symptom during the first few days post-vaccination would be a single unrecognized seizure episode, and only weeks later would the vaccinee exhibit more noticeable neurologic symptoms. (*Id.* at 167-168.) In other words, in a situation where pertussis vaccine had caused a long-lasting injury, he would expect to see severe, dramatic neurologic signs within a few days, followed thereafter either by improvement or stability of the neurologic condition. He would not expect negligible initial symptoms, then a dramatic event weeks later. (*Id.* at 164-169; 199-202.)

On this point, I found Dr. Sladky to be substantially more persuasive than Dr. Geier. Dr. Sladky's outstanding credentials as a pediatric neurologist give him superior credibility on this point. He is much more qualified than Dr. Geier to opine as to the issue of what would likely be the initial symptoms of a chronic *neurologic* injury. Moreover, Dr. Geier simply failed to explain persuasively how the pertussis vaccine might so severely injure a brain without causing severe symptoms within the first few days.

Accordingly, for all the reasons set forth above, I find that Dr. Geier has failed to demonstrate the validity of his *basic theory* for determining that particular neurologic injuries were caused by a pertussis vaccination.

ADDITIONAL DISCUSSION OF GENERAL ISSUE
OF WHETHER THE PERTUSSIS VACCINE
CAUSES CHRONIC NEUROLOGIC INJURY

In part III of this Decision, I set forth my reasons for concluding that petitioner has failed to demonstrate that the chronic neurologic dysfunction of *Caroline Lewis* was vaccine-caused. In this section, however, I wish to add a brief discussion concerning *the general* issue of whether the pertussis vaccine causes chronic neurologic injury, and, if so, in what circumstances it can be determined, in a Program case, that a particular individual's neurologic dysfunction was vaccine-caused.

There is little doubt that this general question has been, and will be, an exceedingly important one under the Program. The whole-cell pertussis vaccine was essentially the exclusive form of pertussis vaccination in this country until only a couple of years ago, and still is being received today by many children. Moreover, because of recent changes in the Program, this issue will become important in many more Program cases than was true during the initial years of the Program's existence. That is because in 1995 and again in 1997, the Secretary of Health and Human Services promulgated administrative changes to the "Vaccine Injury Table" mentioned above. See 60 Fed. Reg. 7678 (1995); 62 Fed. Reg. 7685 (1997). With respect to the DPT vaccine, these changes, *inter alia*, eliminated "seizure disorder" as a Table Injury, and also radically narrowed the scope of the "encephalopathy" Table Injury category. Accordingly, many cases that would formerly have fit within these Table Injury categories, cases involving seizures or other serious neurologic symptoms manifested *very soon* after such vaccinations, will undoubtedly in the very near future raise difficult questions of "actual causation."

Thus, with this type of issue looming in numerous Program cases, I wish to clarify, in this section of this Decision, exactly what questions I *am* and *am not* addressing in this Decision.

First, I *have* in fact, in part III(B)(3) of this Decision, squarely addressed, and rejected, what I have termed Dr. Geier's own personal theory of when one can deem a case of chronic neurologic dysfunction to have been caused by a pertussis vaccination. As explained at those pages, Dr. Geier has failed to explain to my satisfaction why it is reasonable to consider a chronic neurologic condition to be vaccine-caused in the absence of any strong evidence of serious neurologic injury occurring within the first few days post-vaccination.

It should also be clear, however, that in this case I have *not* reached a conclusion as to the validity of a *separate*, somewhat less sweeping causation theory that apparently has been advanced by a number of experts, based in large part upon the original NCES, the 1993 NCES follow-up study, and the 1994 IOM

Report conclusion quoted at p. 7 above. That is, some petitioners have argued that if a neurologically-intact child (1) suffers, within seven days after a pertussis vaccination, a neurologic episode that would have qualified that child as a "case child" under the NCES, (2) goes on to develop chronic neurologic dysfunction, and (3) no other cause for that dysfunction can be identified, then it is appropriate to attribute the chronic neurologic condition to the vaccination. As I explained above (pp. 6-8), I did not need to reach a conclusion as to the validity of *that* general causation theory in this case, because Caroline Lewis did *not* suffer such a "serious acute neurologic illness" within seven days of a DPT vaccination. In my mind, the question of whether that basic theory is a valid one remains an *open* question.

V

CONCLUSION

The story of Caroline Lewis and her severe neurologic condition is a tragic one. Her mother, who testified before me, seems to be a good person, admirably devoted to Caroline's welfare. Congress, however, designed the Program to compensate only those individuals who can demonstrate either a causal or defined temporal link between their injuries and a listed vaccination. And in this case the petitioner has failed to demonstrate such link with respect to Caroline's condition, for the reasons discussed above. Therefore, I conclude that petitioner is not entitled to a Program award. [\(8\)](#)

George L. Hastings, Jr.

Special Master

1. The applicable statutory provisions defining the Program are found at 42 U.S.C. § 300aa-10 *et seq.* (1994 ed.). Hereinafter, all "§" references will be to 42 U.S.C. (1994 ed.).
2. "C.F.R." references in this opinion are to the 1996 edition of the C.F.R.
3. It may be noted that a second administrative revision to the Vaccine Injury Table was promulgated in 1997. *See* 62 Fed. Reg. 7685, 7688 (1997) (to be codified at 42 C.F.R.). That version of the Table is not applicable to this case, however, since it applies only to Program petitions filed after March 24, 1997.
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).

5. In very recent years, a new type of "acellular" pertussis vaccine has become available, and is being substituted for the whole-cell pertussis vaccine in many DPT inoculations. In the balance of this opinion, however, when I refer simply to the "pertussis vaccine," I will be referring to the whole-cell vaccine.

6. I note that in remarks at the conclusion of the hearing in this case on September 30, 1997, I indicated that it is probable that the first of the *unusual jerking movements* by Caroline, reported by Caroline's mother in December of 1992 to have occurred in the previous weeks, occurred about four or five days after her DPT vaccination on November 5, 1992. (Tr. 9-30-97 at 83.) I stated no conclusion at that time, however, as to whether such movements constituted *seizure activity*.

I also stress that even if I were to *assume* that the unusual movements were seizures, with the first of them occurring about four days post-vaccination, the outcome of this case would be no different. That is, as I will explain at pp. 6-8, below, the occurrence of a single subtle seizure would not mean that Caroline suffered a "serious acute neurologic illness" within seven days of her vaccination, and thus the 1994 IOM Report would not support a vaccine-causation conclusion in her case. Further, while such a single seizure would apparently put Caroline's case within Dr. Geier's *own* theory concerning pertussis causation, I conclude that the record in this case does not offer significant support for that theory, for the reasons stated at pp. 8-10, below.

7. Note that Dr. Sladky confirmed that Caroline did not experience a "serious acute neurologic illness," within the NCES definition, within seven days after her DPT vaccination in question. (Tr. of hearing on 4-28-99, pp. 182-84.)

8. I do note that, despite the petitioner's ultimate lack of success on this claim, I find that this case was brought "in good faith" and upon a "reasonable basis." Accordingly, petitioner will be entitled to an amount of attorneys' fees and costs incurred in this action pursuant to § 300aa-15(e). This amount will be awarded in a supplemental decision after the judgment "on the merits" becomes final. See Vaccine Rule 13.