In the United States Court of Federal Claims

OFFICE OF SPECIAL MASTERS

No. 98-120V

(Filed: September 7, 2000)

ERIN LIABLE and JOHN LIABLE, as Parents and Natural Guardians of SIERRA LIABLE, a minor,	*	
Petitioners,	*	**TO BE PUBLISHED**
v.	*	
SECRETARY OF HEALTH AND HUMAN SERVICES,	*	
Respondent.	*	

Paul C. Quinn, Philadelphia, Pennsylvania, for petitioners.

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

RULING ON "ENTITLEMENT" ISSUE

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 petitioners' daughter, Sierra Liable. For the reasons stated below, I conclude that petitioners are entitled to such an award on Sierra's behalf, in an amount yet to be determined.

[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.).

I

BACKGROUND FACTS AND PROCEDURAL HISTORY

Sierra Liable, daughter of the petitioners, was born on November 12, 1994. During her first six months of life, Sierra seemed to be generally healthy.

During the morning of May 18, 1995, Sierra received her third DPT (diphtheria, pertussis, tetanus) vaccination at the office of her pediatrician. About five hours later, she began to exhibit unusual movements, and she was rushed back to her pediatrician and then to a hospital. At the hospital, Sierra was diagnosed to have suffered a seizure of between 30 and 60 minutes in duration. The seizure stopped after anti-seizure medication was administered.

On June 25, 1995, Sierra was again hospitalized with an extended seizure. Over the next few months, she suffered several more extended seizures. In addition, other signs of neurologic abnormality began to be noted. Ultimately, as more evidence of abnormality was identified, it became clear that Sierra suffers from a severe neurologic disorder, involving uncontrolled seizures and very significant developmental delay. She still suffers from that disorder, and no cause for that disorder has ever been definitively identified.

On February 13, 1998, the petitioners filed this Program proceeding on Sierra's behalf, contending that Sierra's neurologic disorder was caused by her DPT vaccination of May 18, 1995. Respondent contested petitioners' claim, and considerable evidence was introduced in documentary form. An evidentiary hearing was held on February 8, 2000, 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 24, 1997. See 62 Fed. Reg. 7685, 7688 (1997); *O'Connell v. Shalala*, 79 F. 3d 170 (1st Cir. 1996). That Table modification, along with an earlier administrative modification of the Table in 1995 (see 60 Fed. Reg. 7678 (1995)), significantly altered the "Table Injury" categories with respect to DPT vaccinations from the version of the Table contained in the statute. In this case, the petition originally alleged that Sierra suffered unspecified Table Injuries. By the time of the hearing in this case, however, petitioners acknowledged that under the modified Table applicable to this case, none of the listed Table Injuries are applicable to Sierra's case.

Therefore, the dispute to be resolved here concerns only whether petitioners have demonstrated that it is "more probable than not"[2] that Sierra's seizure disorder and related neurologic problems were *actually caused* by her DPT vaccination administered on May 18, 1995.

III

DISCUSSION

I conclude that petitioners have met their burden of demonstrating that it is "more probable than not" that Sierra's neurologic disorder, including her seizure disorder, was vaccine-caused. I will divide my discussion into several sections below.

A. The required showing

In analyzing a contention of "actual causation," the presumptions available under the Vaccine Injury Table are, of course, inoperative. It is clear that the burden is on the petitioners to show that in fact the vaccination in question more likely than not caused the injury. *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 petitioners 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*, 718 F.2d 202, 205-06 (6th Cir. 1983), *cert. denied* 469 U.S. 817 (1984); *Novak v. United States*, 865 F.2d 718, 724 (6th Cir. 1989). The petitioners need not show that the vaccination was the sole cause or even the predominant cause of the injury or condition, but they must demonstrate that the vaccination was at least a "substantial

[2]Petitioners have 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).

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 relevant medical literature

The general topic of whether the whole-cell pertussis vaccine[3] can cause chronic neurologic damage to a vaccinee has been a source of controversy and medical study for a number of decades. A good description of the history of that vaccine, and the evidence with respect to the possibility of adverse reactions thereto, is contained in a document to which I will refer as the "1991 IOM Report." That report, entitled *Adverse Effects of Pertussis and Rubella Vaccines* (National Academy Press, 1991), was produced by a committee of physicians selected by the Institute of Medicine ("IOM"), the medical arm of the National Academy of Sciences, for the express purpose of assisting Program officials in making determinations relevant to the Program. Excerpts from the 1991 IOM Report were placed into the record of this case as respondent's Ex. C (filed December 10, 1998). I will not attempt to repeat the entire history of the controversy surrounding the pertussis vaccine that is contained in the 1991 IOM Report, but I will highlight it briefly. The first report of potential adverse reactions to the pertussis vaccine was published in 1933, with a number of additional reports surfacing in the late 1940's, and numerous medical articles concerning the topic have been published since that time. A number of studies and articles have shed important light on the topic, but the largest and most important study was a British study known as the "National Childhood Encephalopathy Study" (hereinafter "NCES"), the results of which were published in 1981.[4]

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[3]Until very recent years, the only type of pertussis vaccine in general use was the whole-cell pertussis vaccine. In the last several years, a new type of "acellular" pertussis vaccine has become available, and is now being substituted for the whole-cell pertussis vaccine in most DPT inoculations in this country. In the balance of this opinion, however, when I refer simply to the "pertussis vaccine," I will be referring to the whole-cell vaccine. Further, when I refer to the "DPT vaccine," I will refer to DPT vaccine containing the whole-cell pertussis vaccine.

There is no dispute that the DPT vaccination received by Sierra Liable on May 18, 1995, included the whole-cell pertussis vaccine. (Combined vaccinations containing the acellular pertussis vaccine are normally described as "DTaP" vaccinations.)

[4]A copy of the 1981 formal report of the study, to which I will refer as the "1981 NCES report," is filed in this case as respondent's Ex. F. That report is generally cited as follows: Alderslade, Bellman, Rawson, Ross, and Miller, "The National Childhood Encephalopathy Study: A report on 1000 cases of serious neurological disorders in infants and young children from the NCES research team." This report was part of a larger report entitled *Whooping Cough: Reports from the Committee on the Safety of Medicines and the Joint Committee on Vaccination and Immunization* (Department of Health and Social Security, London: Her Majesty's Stationery Office, 1981.)

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

> 1. Acute or subacute encephalitis, encephalomyelitis, [or] 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. D (1994 IOM Report) at 6.) 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 8.) The researchers determined that the frequency of neurologic incidents of the type specified 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*.) Specifically, the NCES data indicated that children vaccinated with DPT had a risk of experiencing a "severe acute neurologic illness" in the following seven days that was about 3.3 times as great as the risk that a non-vaccinated child of similar age would have of experiencing a "severe acute neurologic illness" within a given seven-day period. (*Id*.)

The 1991 IOM committee studied the NCES data, and all other available evidence concerning the potential relationship between the pertussis vaccine and neurologic injury. Based in large part upon the NCES, the 1991 IOM committee concluded that the medical evidence is "consistent with a causal relation between DPT vaccine and *acute encephalopathy*." (Ex. C (1991 IOM Report) at 118, emphasis added.) ("Encephalopathy" indicates brain dysfunction; "acute" indicates a short-term incident as opposed to a chronic condition.) The 1991 IOM committee also concluded, however, 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*.)

Scientific study of this general causation issue continued, of course, after publication of the 1991 IOM Report. Most significantly, 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.[5] Publication of this 1993 study prompted

[5]The full formal report of the 1993 NCES follow-up study, contained in the record here as respondent's Ex. G (filed Dec. 10, 1998), is cited as Madge, Diamond, Miller, Ross, McManus,

the Institute of Medicine to again convene a committee of physicians, to review the conclusions of the 1991 IOM committee in light of the 1993 study. That newly-convened IOM committee (to which I will hereinafter refer as the "1994 IOM committee") reviewed the 1993 NCES follow-up study in conjunction with the evidence that the 1991 IOM committee had reviewed, and then issued a report to which I will refer as the "1994 IOM Report."[6] 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 incidents--with the lesson of the 1993 NCES follow-up study--*i.e.*, that persons who suffer severe *acute* neurologic incidents as small children are at a considerably increased risk for *chronic* neurologic dysfunction. Putting these two results together, the 1994 IOM committee reached the conclusion 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. D (1994 IOM Report) at 15, emphasis in original.)

This conclusion of the 1994 IOM Report quoted immediately above, as will be seen, has become crucial to resolution of a number of Program cases in recent years, and is the key to the outcome of this case as well.

C. Summary of expert testimony

Petitioners rely chiefly upon the testimony and documentary evidence supplied by their medical expert, Dr. S. Charles Bean, a physician specializing in pediatric neurology who has been Sierra's primary treating neurologist since the onset of her condition. Dr. Bean supplied petitioners' Exs. 22 and 34, which contain his written analysis of Sierra's case. Dr. Bean also testified orally at the evidentiary hearing held on February 8, 2000.

Dr. Bean testified that he is generally familiar with the evidence concerning the issue of whether the whole-cell pertussis vaccine, which was part of the DPT inoculation that Sierra received,

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Wadsworth, and Yule, "The National Childhood Encephalopathy Study: A 10-year follow-up. A report of the medical, social, behavioral and educational outcomes after serious, acute, neurological illness in early childhood." *Developmental Medicine and Child Neurology* 1993; Supplement No. 68:35(7):1-118.

[6]The 1994 IOM Report, contained in the record here as respondent's Ex. D (filed Dec. 10, 1998), was formally entitled "DPT Vaccine and Chronic Nervous System Dysfunction: A New Analysis" (National Academy Press, 1994). I note that this "1994 IOM Report" is a document *distinct* from another, lengthier report issued by a separate IOM committee that was also released in 1994, entitled *Adverse Events Associated with Childhood Vaccines* (National Academy Press, 1994).

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 Sierra.

Dr. Bean explained that his opinion depends in large part upon the fact that Sierra's first seizure, a very lengthy one, took place just hours after her DPT vaccination on May 18, 1995. He also stressed that a thorough medical work-up has failed to identify any other cause for Sierra's chronic neurologic disorder. Dr. Bean believes that, in these circumstances, it is more probable than not that Sierra's chronic abnormality was caused by the pertussis vaccine.

Dr. Bean discussed the document which I have described above as the "1994 IOM Report." Dr. Bean 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. D, p. 15.) Dr. Bean opined that by this statement the 1994 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. Bean opined that Sierra's case fits within this category of cases, and, thus, that the 1994 IOM Report should be viewed as supportive of the conclusion that Sierra's chronic neurologic dysfunction was vaccine-caused.

Respondent, on the other hand, relied chiefly upon the testimony of Dr. John T. MacDonald, who supplied a written report filed as respondent's Ex. A (filed Oct. 7, 1998), and also testified at the hearing on February 8, 2000. Dr. MacDonald, also a pediatric neurologist, opined that it is incorrect to conclude that Sierra's chronic neurologic condition was vaccine-caused.

Dr. MacDonald argued that the particular facts of Sierra's medical history make it unlikely that her condition was caused by her pertussis vaccination. Dr. MacDonald stressed his belief 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 Sierra has suffered, he would expect to see more symptoms in the period immediately following the vaccination than the single seizure from which Sierra suffered. He would expect to see a severe "acute encephalopathy," meaning that the child would experience a considerable time period of severely altered mental status, such as a coma or changes in the child's interaction with her environment. He would also expect that any changes in the child's developmental ability caused by a vaccine reaction would be obvious in the period *immediately* after the reaction, rather than manifesting themselves months later, as was apparently the case with Sierra.

D. Relevant legal opinions

Over the history of the Program, the question of whether the pertussis vaccine causes chronic or permanent neurologic injury--and, if so, in what circumstances an individual case of neurologic injury can be deemed to have been vaccine-caused--has been a very important one. In fact, a substantial majority of the petitions that have been filed in the Program's twelve-year history have

involved an allegation that a recipient of a DPT inoculation, containing the whole-cell pertussis vaccine, suffered death or serious neurologic injury as a result of the vaccination. A significant number of published Program decisions have addressed that general question. Accordingly, it seems appropriate that, in deciding this case, I review the history of such Program decisions. I will divide that review into several sections below.

1. Special master decisions in early Program years

For much of the Program's early history, the general issue of whether the pertussis vaccine *actually causes* neurologic injury actually turned out, somewhat surprisingly, to be of crucial importance in only a relative handful of cases, because of the Program's "Table Injury" provision described above. That is, with respect to individuals who had suffered neurologic injuries after DPT vaccination, and who filed their Program petitions prior to March 10, 1995, resort to the Vaccine Injury Table was usually sufficient to resolve the case. There existed three Table Injury categories which often applied to persons who died or suffered neurologic injuries after DPT vaccination--*i.e.*, the "residual seizure disorder," "encephalopathy," and "shock-collapse" Table Injuries. See § 300aa-14(a)(I)(B), (C), and (D). Pursuant to those Table Injury provisions, persons who could demonstrate that they suffered seizures or other significant signs of neurologic injury within three days of a DPT vaccination received Program compensation under the *statutory presumption* of causation, without the need for demonstrating that the vaccination *actually caused* the injury. Other petitioners, who failed to demonstrate that their cases fit within one of those Table Injury categories, usually either did not allege "actual causation" as an alternative theory of entitlement, or else failed to present any significant evidence supporting an "actual causation" claim.

However, a few published decisions during the early years of the Program did contain discussion of the issue of whether the pertussis vaccine "actually caused" the vaccinee's injury. In cases in which the vaccinee's first significant neurologic symptoms were found to have occurred *more than seven days* after DPT vaccination, the decisions generally found that the petitioners had *failed* to demonstrate that the vaccination had caused the vaccinee's neurologic disorder. See, *e.g.*, *Summar v. Secretary of HHS*, No. 90-415V, 1991 WL 133607 (Cl. Ct. Spec. Mstr. July 3, 1991); *Rous v. Secretary of HHS*, No. 90-794V, 1991 WL 92942 (Cl. Ct. Spec. Mstr. May 16, 1991); *Saunders v. Secretary of HHS*, No. 90-826V, 1991 WL 274235 (Cl. Ct. Spec. Mstr. Dec. 9, 1991).[7]

In cases in which the first significant symptoms of neurologic damage occurred *more than three days but no more than seven days* after vaccination, on the other hand, the results were mixed.

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[7]I have found only one exception. In *Grant v. Secretary of HHS*, No. 88-70V, 1990 WL 293410 (Cl. Ct. Spec. Mstr. July 13, 1990), *aff'd* 956 F. 2d 1144 (Fed. Cir. 1992), the vaccinee's neurologic disorder was found to be vaccine-caused although his first seizure did not take place until about 10 days after his pertussis vaccination. This ruling, however, was heavily dependent on the fact that this particular pertussis vaccination came as part of the four-part "Quadrigen" inoculation, not an ordinary three-part DPT inoculation, and certain evidence indicated that this particular type of vaccination was significantly more likely to cause injury than an ordinary DPT immunization.

A number of decisions, issued by a wide variety of special masters, found that "actual causation" had, in fact, been demonstrated in such instances. *See, e.g., Sharpnack v. Secretary of HHS*, No. 90-983V, 1992 WL 167255, at *6 (Cl. Ct. Spec. Mstr. French, June 29, 1992), *aff'd* 27 Fed. Cl. 457 (1993), *aff'd* 17 F. 3d 1442 (Fed. Cir. 1994); *Loe v. Secretary of HHS*, No. 89-83V, 1990 WL 292877 (Cl. Ct. Spec. Mstr. Wright, Aug. 1, 1990); *Wolf v. Secretary of HHS*, No. 90-3137, 1994 WL 142295 (Fed. Cl. Spec. Mstr. French, April 7, 1994); *Bush v. Secretary of HHS*, No. 89-39V, 1990 WL 293443 (Cl. Ct. Spec. Mstr. Hauptly, July 6, 1990); *Hulsey v. Secretary of HHS*, No. 88-46, 1989 WL 250135, at *10 (Cl. Ct. Spec. Mstr. Golkiewicz, Oct. 13, 1989); *Bailey v. Secretary of HHS*, No. 88-56, 1989 WL 250113, at *5-6 (Cl. Ct. Spec. Mstr. Gerard, Sept. 6, 1989); *Latorre v. Secretary of HHS*, No. 89-27, 1990 WL 290313 at *2, *4 (Cl. Ct. Spec. Mstr. Baird, June 15, 1990); *Sumrall v. Secretary of HHS*, No. 90-135, 1991 WL 20074 at *5 (Cl. Ct. Spec. Mstr. French, Jan. 10, 1991), aff'd 23 Cl. Ct. 1 (1991); *Candelas v. Secretary of HHS*, No. 90-759, 1991 WL 187316, at *4 (Cl. Ct. Spec. Mstr. Baird, Sept. 5, 1991); *Estep v. Secretary of HHS*, No. 90-1062, 1992 WL 357811, at *6 (Fed. Cl. Spec. Mstr. Baird, Nov. 3, 1992), *aff'd* 28 Fed. Cl. 664 (1993).[8] Some of these decisions, such as *Sharpnack*, contained lengthy analysis of the medical literature then available, such as the original NCES report. Others cited simply to the persuasiveness of medical expert testimony offered by the petitioner. Note that in some of these early cases the respondent did not participate at all in the proceedings, so that the only expert opinion put before the special master was the opinion of the petitioner's expert.

In a number of other Program cases, in which the onset of symptoms occurred between four and seven days post-vaccination, however, special masters found that the available evidence was *insufficient* to justify a finding of actual causation. See, *e.g., Parks v. Secretary of HHS*, No. 90-268V, 1991 WL 33233 (Cl. Ct. Spec. Mstr. Hastings, Feb. 21, 1991); *Ultimo v. Secretary of HHS*, No. 90-2045V, 1992 WL 392629 (Fed. Cl. Spec. Mstr. Golkiewicz, Dec. 11, 1992), *aff'd* 28 Fed. Cl. 148 (1993); *Ormechea v. Secretary of HHS*, No. 90-1683V, 1992 WL 151816 (Cl. Ct. Spec. Mstr. Millman, June 10, 1992); *Haim v. Secretary of HHS*, No. 90-1031V, 1993 WL 346392 (Fed. Cl. Spec. Mstr. Millman, Aug. 27, 1993); *Schell v. Secretary of HHS*, No. 90-3243, 1994 WL 71254 (Fed. Cl. Spec. Mstr Baird, Feb. 22, 1994).

2. Special master decisions in recent years

In the mid-1990's, however, significant developments, both within the Program and outside of it, substantially affected the analysis in Program cases concerning the issue of whether the pertussis vaccine causes chronic neurologic damage. First, in the Program itself, the key development was the administrative change made to the Vaccine Injury Table in 1995. That is, for Program cases filed after March 10, 1995, the Table Injury categories were substantially modified with respect to the DPT vaccination and other vaccinations that include the pertussis vaccine. See 60 Fed. Reg. 7678 (1995); *O'Connell v. Shalala*, 79 F.3d 170 (1st Cir. 1996). The former Table

[8]See also *Lee v. Secretary of HHS*, No. 90-15, 1990 WL 293861 (Cl. Ct. Spec. Mstr. Wright, Oct. 15, 1990), in which the special master concluded, without ruling as to whether a "Table Injury" had occurred, that a vaccinee's death less than 24 hours after a DPT vaccination was vaccine-caused.

Injuries of "residual seizure disorder" and "shock-collapse" were removed from the Table entirely, while the definition of the "encephalopathy" Table Injury was drastically narrowed. *See* 42 C.F.R. § 100.3(a)(I) (1996 version of C.F.R.). This 1995 change to the Table (which remained in effect when a few additional minor modifications to the Table were made in 1997--see 62 Fed. Reg. 7685 (1997)) radically changed the focus of most Program cases involving pertussis vaccinations. That is, prior to that 1995 Table change, if a previously neurologically-normal person exhibited any significant symptoms of neurologic injury, including seizures, within three days of a DPT vaccination, and then went on to suffer from a chronic neurologic disorder, such person's chronic disorder would likely be found to be presumptively vaccine-caused, pursuant to the Table, unless it was affirmatively shown that some other specific factor caused the disorder. But after the 1995 Table change, there would be a number of Program cases in which seizures or other significant neurologic symptoms appeared within three days or even a few hours or minutes after a DPT vaccination, yet such symptoms would *not* be deemed presumptively-caused, so that the Program petitioner would need to prove that the vaccination *actually caused* the neurologic disorder.

The second major development was the publication of two significant medical articles discussed above--*i.e.*, the NCES follow-up study in 1993, and the 1994 IOM Report in the following year. As previously explained (p. 6), the 1994 IOM Report, putting the 1993 NCES follow-up study together with the previously available evidence, reached the conclusion 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. D (1994 IOM Report) at 15, emphasis omitted). This conclusion significantly bolstered the argument that one could find a vaccinee's chronic neurologic dysfunction to be DPT-caused, at least in situations in which the vaccinee experienced a "serious acute neurologic illness" within seven days of receiving the DPT vaccine.

Thus, since 1995, a number of special master opinions have indicated at least general approval of a causation theory based upon the 1994 IOM Report's conclusion quoted above. That theory can be described generally as follows: 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 causally attribute the chronic neurologic condition to the vaccination. I will hereinafter refer to that general theory as the "1994 IOM causation theory." That theory was adopted, and applied in Program petitioners' favor, by Special Master French in *Oetting v. Secretary of HHS*, No. 95-785, 1999 U.S. Claims LEXIS 1948, at *24-44 (Fed. Cl. Spec. Mstr. June 11, 1999); and also in *Almeida v. Secretary of HHS*, No. 96-412V, 1999 WL 1277566, at *14-21 (Fed. Cl. Spec. Mstr. Dec. 20, 1999). The same theory was also explicitly adopted by Special Master Wright in *Castillo v. Secretary of HHS*, 95-0652V, 1999 WL 605690, at *11 (Fed. Cl. Spec. Mstr. July 19, 1999), although the vaccinee in that case was not found

to qualify for a Program award since that vaccinee did not suffer a "serious acute neurologic illness" of the type described in the NCES within the seven-day post-vaccination period.

The theory also seems to have been adopted by Special Master Abell in *Terran v. Secretary of HHS*, No. 95-451, 1998 WL 55290, at *10-11 (Fed. Cl. Spec. Mstr. Jan. 23, 1998), *aff'd* 41 Fed. Cl. 330 (1998), *aff'd* 195 F. 3d 1302 (1999), in which that master cited the above-quoted conclusion of the 1994 IOM Report with respect to "chronic nervous system dysfunction" (1998 WL 55290 at *10), then stated that he "accepts the theory of causation proffered in the 1991 & 1994 IOM reports" (*id*. at *11). As with *Castillo*, however, the particular claim in *Terran* was denied, because the vaccinee in that case suffered only very brief seizures within the seven-day post-vaccination period, not one of the "serious acute neurologic illnesses" described in the NCES. (*Id*. at *12.)

In addition, yet another special master has given indication of general acceptance of the same theory. In *Williams v. Secretary of HHS*, No. 94-1005V, 1997 WL 803112 (Fed. Cl. Spec. Mstr. Dec. 10, 1997), *aff'd* 194 F. 3d 1334 (Fed. Cir. 1999), Chief Special Master Golkiewicz noted that "it has been held that a DPT vaccination can cause neurological injury up to seven days post-vaccination," cited the 1993 NCES follow-up study and the 1994 IOM Report's conclusion quoted above, and stated that he does not consider the general question of whether "DPT [can] cause a seizure or encephalopathy four days post-vaccination" to even be "at issue." 1997 WL 803112 at *8. Similarly, in *McCarren v. Secretary of HHS*, No. 92-764V, 1997 WL 341694, at *12 (Fed. Cl. Spec. Mstr. June 6, 1997), *aff'd* 40 Fed. Cl. 142 (1997), that same master stated that--

> the court has consistently recognized and upheld certain medical literature findings on this point, namely that it is medically possible for an encephalopathic reaction and/or the onset of a residual seizure disorder to occur following a DPT vaccination, and indeed up to 7 days following the shot, as the NCES literature argues.

To be sure, in each of those two cases a Program award was denied, because in each case the vaccinee suffered only very brief seizures about four days after vaccination, rather than a "serious acute neurologic illness" as defined by the NCES. However, the point remains that both these opinions seemed to indicate a general favorable disposition by that special master to the "1994 IOM causation theory" discussed above.[9]

On the other hand, one recent special master decision declined to find vaccine causation in a case that would seem to fall within the "1994 IOM causation theory." That is, in *Clements v. Secretary of HHS*, No. 95-484V, 1998 WL 481881 (Fed. Cl. Spec. Mstr. July 30, 1998), Special Master Millman declined to find vaccine-causation in a case in which the vaccinee suffered a 45-minute seizure less than 24 hours after vaccination. (1998 WL 481881 at *1, 11.) The special

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[9]I note, however, that in a later decision the Chief Special Master added discussion that makes it appear unclear whether he would be willing to apply the "1994 IOM causation theory" in situations in which the vaccinee's initial seizure was *unaccompanied by fever*. See *Salmond v. Secretary of HHS*, No. 91-123V, 1999 WL 778528, at *5-10 (Fed. Cl. Spec. Mstr. Sep. 16, 1999).

master specifically considered the original NCES study, the 1993 NCES follow-up study, "as well as other [unspecified] epidemiologic literature," as possible support for the petitioner's claim in that case, but found the literature insufficient to support a causation finding. (*Id.* at *14-15.) However, it is not clear that the special master in *Clements* considered the specific conclusion of the 1994 IOM Report upon which the "1994 IOM causation theory" is based. Moreover, it is important to note that in three other recent decisions, the same special master has found that chronic neurologic disorders or deaths *were* "actually caused" by DPT vaccinations. See *McMurry v. Secretary of HHS*, No. 95-682V, 1997 WL 402407 (Fed. Cl. Spec. Mstr. June 27, 1997); *Priest v. Secretary of HHS*, No. 95-134V, 1998 WL 928424 (Fed. Cl. Spec. Mstr. Dec. 7, 1998); *Sword v. Secretary of HHS*, No. 90-1491V, 1998 WL 957201 (Fed. Cl. Spec. Mstr. Dec. 29, 1998), *aff'd* 44 Fed. Cl. 183 (1999).[10] This indicates that while this special master may not fully subscribe to the precise theory that I have dubbed the "1994 IOM causation theory," she does believe that sufficient evidence exists in the medical literature to support a conclusion that the pertussis vaccine can cause chronic neurologic dysfunction in at least some circumstances.

3. Decisions of reviewing courts in Program cases

In my discussion above, I have analyzed only the rulings of the *special masters* of this court in Program cases. Of course, special master decisions are subject to review by judges of the U.S. Court of Federal Claims, whose rulings are, in turn, appealable to the U.S. Court of Appeals for the Federal Circuit. §§ 300aa–12(e) and (f). However, rulings with respect to "actual causation" are factual findings, and factual conclusions of special masters are to be upheld upon review unless found to be "arbitrary or capricious." § 300aa-12(e)(2)(B); see also *Hines v. Secretary of HHS*, 940 F. 2d 1518, 1528 (Fed. Cir. 1991); *Henkel v. Secretary of HHS*, 42 Fed. Cl. 528 (1998); *Lankford v. Secretary of HHS*, 37 Fed. Cl. 723 (1996). Thus, under this deferential standard of review, the differences in analysis among the special masters, in the cases cited above, have not been resolved by the courts reviewing such decisions. Instead, the various factual decisions, though some may have been somewhat contradictory of others, have each been affirmed as constituting factual decisions which were not "arbitrary and capricious." See, *e.g.*, *Grant v. Secretary of HHS*, 956 F. 2d 1144 (Fed. Cir. 1992); *Sumrall v. Secretary of HHS*, 23 Cl. Ct. 1 (1991); *Mobley v. Secretary of HHS*, 22 Cl. Ct. 423 (1991); *Estep v. Secretary of HHS*, 28 Fed. Cl. 664 (1993); *Sharpnack v. Secretary of HHS*, 27 Fed. Cl. 457 (1993), *aff'd* 17 F. 3d (Fed. Cir. 1994); *McCarren v. Secretary of HHS*, 40 Fed. Cl. 142 (1997); *Terran v. Secretary of HHS*, 41 Fed. Cl. 330 (1998), *aff'd* 195 F. 3d 1302 (Fed. Cir. 1999); *O'Connell v. Secretary of HHS*, 40 Fed. Cl. 891 (1998); *Cucuras v. Secretary of HHS*, 26 Cl. Ct. 537, 543 (1992), *aff'd* 993 F. 2d 1525 Fed. Cir. (1993); *Ultimo v. Secretary of HHS*, 28 Fed. Cl. 148 (1993); *Sword v. U.S.*, 44 Fed. Cl. 183, 189 (1999); *Lampe* v. *Secretary of HHS*, No. 99-5050, published cite not yet available (Fed. Cir. July 31, 2000).

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[10]I have also identified two other recent published decisions in which Special Master Millman resolved DPT-causation issues, denying the petitioner's claims in each. See *O'Connell v. Secretary of HHS*, No. 96-63V, 1998 U.S. Claims LEXIS 28 (Fed. Cl. Spec. Mstr. Feb. 2, 1998), *aff'd*, 40 Fed. Cl. 891 (1998); *Valois v. Secretary of HHS*, No. 97-433V, 1998 WL 774342 (Fed. Cl. Spec. Mstr. Oct. 9, 1998).

A pair of somewhat unusual appellate decisions with respect to actual causation, however, are worthy of a brief note. In *Bunting v. Secretary of HHS*, 19 Cl. Ct. 738 (1990) , a special master, relying on the opinion of a petitioner's medical expert in a case in which no expert testified for respondent, found (in an unpublished opinion) that the vaccinee's seizure disorder was caused by a DPT vaccination. On review, a judge of the Court of Federal Claims (then known as the Claims Court), relied upon a written opinion of an expert submitted by respondent, and reversed. (*Id*.) On appeal, the Federal Circuit reversed again, reinstating the special master's ruling that the seizure disorder was vaccine-caused. *Bunting v. Secretary of HHS*, 931 F. 2d 867 (Fed. Cir. 1991).

In *Jay v. Secretary of HHS*, 998 F. 2d 979 (Fed. Cir. 1993), both the special master and judge concluded that a vaccinee's death 18 hours after a DPT vaccination was not shown to be vaccine-caused, but the Federal Circuit reversed, concluding that "causation-in-fact" of the death by the vaccination had been shown.

In these two rulings, then, panels of the Federal Circuit did, find that DPT vaccinations "actually caused" a death and a chronic seizure disorder. However, both cases involve highly unusual situations, in which the *only a single medical expert* provided oral testimony in the case, and opined *in favor of causation*. In such circumstances, the appellate court found error by the factfinder below in failing to credit the opinion of the *sole* testifying medical expert. What is important here, rather, is that in neither opinion did the Federal Circuit purport to analyze the entire universe of scientific evidence and render an opinion on the *general* factual issue of whether the pertussis vaccine causes chronic neurologic injury. To the contrary, my research indicates that neither the Federal Circuit, nor any judge of the Court of Federal Claims, has engaged in any such broad analysis in *any* published Program ruling.

4. Relevant rulings in non-Program cases

There certainly has been considerable litigation outside of the Program involving plaintiffs' claims that they have been neurologically injured by pertussis vaccine. Such claims were apparently particularly common during the years just prior to the establishment of the Program, and their existence was a principal reason behind the establishment of the Program. Accordingly, I have researched the published judicial decisions in such non-Program cases, to determine whether they shed any light upon the general question of whether the pertussis vaccine can cause chronic neurologic disorders. However, as is the case with respect to the decisions of the *reviewing courts* under the Program (see discussion immediately above), these non-Program published rulings generally do not shed much light on the issue. While some published opinions have been generated by such non-Program tort suits, I have been able to identify only a relatively small number of such opinions, and in most of those cases the opinions did not discuss the factual causation issue at all, but addressed other issues such as whether the drug manufacturer failed to give adequate warning of possible dangers of the vaccine, whether the vaccinee's physician acted negligently in administering the drug, etc. Only a handful of the published decisions have even discussed the causation issue, and even those do not contain any substantial discussion of the available evidence concerning that issue. It seems likely that the reason for this absence of discussion of the causation

issue is that most of those claims were tried before juries, which meant that there would be no written trial court opinion on the factual causation issue, while the appellate court would likely merely affirm such jury verdict if it was based on any substantial evidence, without stating its own factual analysis of the issue.

One oft-quoted decision did involve a case tried to a judge, who wrote an extensive opinion explaining his conclusion that an immunization containing the pertussis vaccine likely did cause permanent brain damage to an infant vaccinee. See *Tinnerholm v. Parke-Davis and Co.*, 285 F. Supp 432, 437-440 (S.D.N.Y. 1968), *aff'd* 411 F. 2d 48 (2nd Cir. 1969). That judge's analysis, however, is of limited value here, however, since it was specific to the pertussis vaccine in its form as combined in the ill-fated four-part "Quadrigen" immunization, which was believed to be much more likely than standard DPT vaccines to cause injury. A similar ruling, in which another judge found that the Quadrigen vaccine damaged a vaccinee, was *Stromsodt* v. *Parke-Davis and* Co., 257 F. Supp. 991, 994 (D.N.D. 1966), *aff'd* 411 F. 2d 1340, 1344-47 (8th Cir. 1969). See also, *Ezagui* v. *Dow Chemical Corp.*, 598 F. 2d 727, 733-36 (2d Cir. 1979) (on the issue of whether the Quadrigen vaccine injured the vaccinee, there was sufficient evidence to submit the case to a jury).

The other identified published decisions that even touch on the causation issue do not delve deeply or directly into the substance of that issue. One appellate court decision simply upheld, as "not clearly erroneous," a jury verdict finding that a DPT vaccine caused neurologic injury. *Graham v. Wyeth Laboratories*, 906 F. 2d 1399, 1404 (10th Cir. 1990). One trial court decision simply concluded, in a similar suit, that the evidence for causation was sufficient to go to a jury. *Pease v American Cynanamid Co.*, 795 F. Supp. 755, 758 (D. Md. 1992). Most of the other published decisions contain even less substantive discussion of the causation issue. For example, in *Rohrbough v. Wyeth Laboratories*, 719 F. Supp. 470 (N.D.W.Va. 1989), *aff'd* 916 F. 2d 970 (4th Cir. 1990), the trial judge dismissed a suit alleging that the plaintiff's seizure disorder was caused by a vaccination, on the ground that plaintiff's experts in their deposition testimony simply had failed to opine that the vaccination had caused the disorder. In *Baker v. Lederle Laboratories*, 696 S.W. 2d 890 (Ct. App. Tenn. 1985), a state appellate court ruled, in a case involving an allegation that a DPT vaccination injured a vaccinee, simply that summary judgment against the plaintiff on the causation issue was inappropriate where the plaintiff had offered an affidavit of a qualified expert witness in support of vaccine-causation. In *Stigliano v. Connaught Laboratories*, 140 N.J. 305, 658 A. 2d 715 (N.J. 1995), in another case involving the allegation that a seizure disorder was DPT-caused, the court ruled only that the vaccinee had no right to exclude the testimony of her treating physicians concerning the causation issue. And in *Bock v. Yoder*, 518 So. 2d 1139 (Ct. App. La. 1988), a state trial judge dismissed a suit alleging that a DPT vaccination caused the vaccinee's injury, where the vaccinee's expert supported a causation conclusion only under a factual assumption (concerning the onset of symptoms) which was materially *different* from the facts to which the plaintiff's own witnesses testified.

In sum, the published non-Program court decisions that I have found relating to the pertussis vaccination simply do not shed significant light upon the causation issue that I face in this case.

5. Summary as to prior legal opinions

To summarize my discussion of Program and non-Program published decisions with respect to the issue of whether the pertussis vaccine causes chronic neurologic disorders, I believe that three important conclusions may be gleaned from analysis of those decisions.

First, the courts *reviewing* Program special master decisions concerning this issue have *not* attempted to impose any particular analysis. These reviewing courts have affirmed both special master decisions ruling in favor of vaccine-causation, and special master decisions ruling in the opposite direction, as rationally based upon reasonable evidence.

Second, over the course of the history of the Program, virtually all of those individuals who have acted as Program special masters have filed at least one published opinion ruling either that the pertussis vaccine has likely caused a chronic neurologic disorder in a particular vaccinee, or that such vaccine is capable of causing chronic neurologic dysfunction.

Third, the published Program decisions in *recent* years indicate that a number of special masters have a favorable view of the causation theory that I have dubbed the "1994 IOM causation theory." See *Oetting*, *Almeida*, *Castillo*, *Terran*, *Williams*, and *McCarren*, *supra*. Only one special master has filed a published opinion rejecting a vaccine-causation conclusion in a case that would seem to fall within the "1994 IOM causation theory" (see *Clements*, *supra*), and that master has nevertheless in other cases found the pertussis vaccine capable of causing chronic neurologic injury (see *McMurry*, *Sword*, and *Priest*).

E. Resolution of this case

As noted above, I have concluded that it is "more probable than not" that Sierra's severe neurologic disorder was caused by her pertussis vaccination received as part of her DPT immunization on May 18, 1995. This conclusion is based upon my review of the relevant medical literature (summarized above in part III(B) of this Ruling), the expert testimony (summarized at part III(C) above, and the facts of Sierra's case (summarized at part I above).

The most important reason for this outcome is that I have come to the conclusion, based upon my review of the entire record, that it is reasonable to adopt the "1994 IOM causation theory," and to apply it to this case. To reiterate, the 1994 IOM Report stated the conclusion that the available 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. D (1994 IOM Report) at 15 (emphasis in original). Based upon that conclusion of the 1994 IOM Report, a number of special masters appear to have adopted, as noted above, essentially the following theory, which I have labeled the "1994 IOM causation theory." That theory is that if a

neurologically-intact vaccinee (1) suffers, within seven days after a pertussis vaccination, a neurologic episode that would have qualified as a "serious acute neurologic illness" under the NCES; (2) goes on to experience chronic neurologic dysfunction of the type described in the NCES; and (3) no other cause for that dysfunction can be identified; then it is appropriate to causally attribute the chronic neurologic dysfunction to the vaccination. I find that the evidence contained in the record here supports the validity of that theory, and supports its application here.

There are a number of points to be made in support of this conclusion. First, I note that the record here clearly supports a determination that the conclusion of the 1994 IOM Report, quoted above, is a reasonable one. The 1994 IOM committee that reached the conclusion was chosen by the prestigious Institute of Medicine, and its members clearly have outstanding credentials relevant to the subject at issue. In addition, my review of the 1994 IOM Report in its entirety makes me conclude that the report's central conclusion--*i.e.*, the conclusion quoted above--was reached in a scientifically reasonable fashion after full consideration of all the relevant data. In short, there simply is nothing in the record raising any serious reason for me not to accept this conclusion of the 1994 IOM Report as an accurate one.[11]

Given that the above-quoted conclusion of the 1994 IOM Report is found to be an accurate one, then, the next question is whether the causation theory that I have set forth above--*i.e.*, the "1994 IOM causation theory," logically follows from the quoted conclusion. After full consideration of all the evidence before me, I conclude that this causation theory *does* logically follow from the conclusion stated in the 1994 IOM Report.

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[11]In some Program cases, the respondent has attacked causation theories based, like the "1994 IOM causation theory," largely upon the NCES, arguing that the NCES was inherently flawed. The respondent has pointed especially to the fact that the total number of children in the NCES who experienced acute neurologic incidents shortly after DPT vaccination was relatively small, meaning that there is some possibility that chance alone accounted for the apparent increased risk of such incidents after DPT vaccination. See, *e.g., Haim v. Secretary of HHS*, *supra*, 1993 WL 346392 at *12-14; *Clements v. Secretary of HHS*, *supra*, 1998 WL 481881 at *14-15. These criticisms are not completely without merit; indeed, the authors of the NCES themselves have stated that conclusions must be drawn from the NCES "with considerable caution," for the reason stated above. Ex. F (1981 NCES report) at 98-99. However, a review of the NCES data and of the learned articles discussing the NCES contained in the record here indicates, on balance, that the NCES was a reasonably well-designed study that used accepted scientific techniques. And while the number of post-vaccination illnesses was not huge, the numbers were sufficient to rise to the level of "statistical significance," using accepted scientific statistical techniques. Further, it is significant that all of the various prestigious IOM committees discussed above have not dismissed the NCES as a flawed study, but, to the contrary, have utilized NCES data in their analyses. Thus, while the NCES data do not prove a causal relationship to the level of *scientific certainty*, I conclude that the NCES supplies evidence that is sufficient upon which to support a conclusion that a causal relationship *probably* exists.

In this regard, it appropriate to first closely examine the conclusion of the 1994 IOM Report, and to explain why I believe that the general causation theory that I have dubbed the "1994 IOM causation theory" follows from the 1994 IOM Report's stated conclusion. Initially, it is noteworthy that the committee concluded that the evidence "is consistent with" a causal relationship between the DPT vaccine and chronic nervous system dysfunction. The committee added immediately thereafter that the conclusion that the evidence "is consistent with" a causal relationship is "not the strongest statement regarding causality; the evidence does not establish or prove a causal relation." (Ex. D. (1994 IOM Report) at 15.) What does the "is consistent with" statement mean, then, if it does not mean that the evidence "establishes" or "proves" a causal relationship? To answer that question, the 1994 IOM Report, in the very next sentence after the one quoted just above, directed the reader to previous IOM reports that were issued in 1991 and 1994. The 1991 IOM Report and the IOM report issued earlier in 1994, entitled "Adverse Events Associated with Childhood Vaccines" (see fn. 6, above), each utilized five separate categories for evaluating the evidence concerning whether a particular vaccination causes a specific condition or injury. The categories used in each report were similar, but not identical. The five categories utilized in the 1991 IOM Report were as follows:

1. No evidence bearing on a causal relation.
2. Evidence insufficient to indicate a causal relation.
3. Evidence does not indicate a causal relation.
4. Evidence is consistent with a causal relation.
5. Evidence indicates a causal relation.

(See 1991 IOM Report at pp. 4, 8 (these particular pages of the 1991 IOM Report do not appear at Ex. C filed in this case).) The five categories utilized in the "Adverse Events" 1994 IOM report were as follows:

1. No evidence bearing on a causal relation.
2. The evidence is inadequate to accept or reject a causal relation.
3. The evidence favors rejection of a causal relation.
4. The evidence favors acceptance of a causal relation.
5. The evidence establishes a causal relation.

("Adverse Events" at 16.) The 1991 IOM Report did not explicitly explain the exact meaning of its five categories, and that generated some confusion. Therefore, in the 1994 "Adverse Events" report, the IOM committee explicitly explained its five categories. (*Id*. at 32-33.) It also explained, most importantly, that the categories utilized in the 1994 "Adverse Events" report "represent the *same concepts* intended by the predecessor committee" in the corresponding categories; the wording changes in the new categories were intended not to change the meaning of the categories, but simply to "clarify" the meaning of the categories. (*Id*. at 16; emphasis added.)

Therefore, with this background in mind, to find the meaning of the "is consistent with" language used in the 1994 IOM Report, we see that the "is consistent with" language constitutes the fourth category under the five 1991 categories, and thus we look to the "clarified" language of the fourth category utilized in the 1994 "Adverse Events" report. We see, then, that the "is consistent

with" language means that the committee found that the evidence "favors acceptance of" a causal relation. And, to me, it seems obvious, from the plain meaning of the words "favors" and "acceptance," that the "favors acceptance of" category means that the committee found it "probable" or "likely," though less than certain, that a causal relationship exists. Therefore, from this chain of reasoning, I conclude that when the 1994 IOM committee used the "is consistent with" language in the conclusion quoted above, it meant that the committee found it "probable" or "likely," though not certain, that a causal relationship exists between the DPT vaccine and chronic nervous system dysfunction, under the specified circumstances. And this level of probability, in my view, is consistent with the legal standard that I am to apply in this case. That is, I am to compensate the petitioners if I find it "more probable than not" that the vaccination caused Sierra's neurologic disorder; I need not conclude that it is *certain* that her disorder is vaccine-caused.

Next, an important consideration is that a subtle distinction may be said to exist between the stated conclusion of the 1994 IOM Report and the causation theory that I am adopting here. That is, the 1994 IOM Report finds it likely that, *in general*, there exists a causal relationship between the DPT vaccine and chronic nervous system dysfunction, in persons who experience a "serious acute neurologic illness" of a defined type within seven days of DPT vaccination. The "1994 IOM causation theory," in effect, goes one step further, in reasoning that if a *particular individual* suffers a "serious acute neurologic illness" within seven days of pertussis vaccination, then goes on to experience chronic neurologic dysfunction of the type described in the NCES, and no other likely cause is identified, it can be said that *such individual's* chronic dysfunction was likely vaccine-caused. However, after careful consideration of all of the evidence and argument concerning the issue, I conclude that the evidence, and principles of logic, justify taking the additional step that the causation theory takes. That is, it seems to me to be inherently logical that if the available medical evidence justifies a conclusion that there probably exists a causal relationship *in general* between the vaccine and chronic neurologic dysfunction in persons who fall within this particular set of circumstances, then in the case of an *individual* whose history falls squarely within that set of circumstances, and in whose case there is no substantial evidence of any other particular potential causative agent, it makes sense to conclude that it is probable--though not certain--that such *individual's* chronic dysfunction was vaccine-caused.

Moreover, it is important that the 1994 IOM committee based its causation conclusion upon an NCES calculation of a "relative risk" factor of *greater than two*. That is, the NCES data indicated that children vaccinated with DPT had a "relative risk" of experiencing a "severe acute neurologic illness" in the following seven days that was about 3.3 times as great as the risk that a non-vaccinated child of similar age would have of experiencing a "severe acute neurologic illness" within a given seven-day period. (Ex. D (1994 IOM Report) at 8.) It has often been noted that where epidemiologic studies have shown a "relative risk" of greater than 2, such studies can support a finding of causal relationship under the "preponderance of the evidence" standard. See, *e.g. Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 43 F. 3d 1311, 1321 (9th Cir. 1995), *cert. denied*, 516 U.S. 869 (1995) (noting that the key inquiry was whether experts could testify that the relative risk was more than doubled); *DeLuca v. Merrell Dow Pharmaceuticals, Inc.*, 911 F. 2d 941, 959 (3rd Cir. 1990) ("a relative risk greater than 2 means that the disease more likely than not was caused by the event"); *In re Joint Eastern and Southern District Asbestos Litigation*, 52 F. 3d 1124, 1128 (2nd Cir. 1995) (even in the absence of "direct proof of causation," the preponderance standard can be met

where the relative risk exceeds two); *Manko v. U.S.*, 636 F. Supp. 1419, 1434 (W.D. Mo. 1986) ("a relative risk of greater than two means that the disease more likely than not was caused by the event"), *aff'd* 830 F. 2d 831 (8th Cir. 1987); *Marder v. G.D. Searle & Co.*, 630 F. Supp. 1087, 1092 (D. Md. 1986) ("[i]n epidemiological terms, a two-fold increased risk is an important showing for plaintiffs to make because it is the equivalent of the required legal burden of proof--a showing of causation by the preponderance of evidence or in other words, a probability greater than 50%"), *aff'd* 814 F. 2d 655 (4th Cir. 1987); *Oetting v. Secretary of HHS*, *supra*, 1999 U.S. Claims Lexis at *35. Thus, the fact that my theory relies principally upon this "relative risk" estimate of 3.3 means that it is statistically reasonable to point to an *individual case* and to say that it is "more likely than not" that such individual's chronic dysfunction was vaccine-caused.

Next, I conclude that the *particular case of Sierra Liable* falls squarely within the "1994 IOM causation theory." The record shows that Sierra was not known to have any significant neurologic abnormality prior to her DPT immunization on May 18, 1995. It is also undisputed that later on the day of that vaccination, Sierra suffered a seizure that lasted more than 30 minutes; this seizure, because it lasted longer than 30 minutes, qualifies Sierra as an individual who suffered a "serious acute neurologic illness" under the NCES definition,[12] within seven days of her DPT vaccination. Third, it is clear that Sierra went on to experience chronic neurologic dysfunction, of the type described in the NCES.[13] Fourth, the record does not contain substantial evidence of a cause for Sierra's chronic neurologic dysfunction other than her DPT vaccination.

Thus, Sierra's case falls squarely within the parameters of the "1994 IOM causation theory," and, therefore, I conclude that it is "more probable than not" that Sierra's chronic neurologic dysfunction was vaccine-caused.

In reaching my conclusion here, I have carefully considered the arguments raised by respondent. First, respondent raised an important concern through the testimony of Dr. MacDonald. That is, as explained above, Dr. MacDonald argued that if a pertussis vaccination were in fact to

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[12]What did the 1994 IOM committee mean by the 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 them as "case children"* under the original NCES. In other words, children who experienced one of the five neurologic events of the type specified in the quotation set forth at p. 5 above. With respect to Sierra's case, I note that one of the five types of neurologic events that qualified children as "case children" under the NCES was a "convulsion [seizure] with a total duration of more than half an hour." Sierra suffered a convulsion of that duration, and thus suffered a "serious acute neurologic illness" within the NCES definition of that term.

[13]Sierra has suffered from a severe chronic neurologic disorder involving seizures and very significant developmental impairment. Her chronic neurologic dysfunction, thus, is clearly comparable to the chronic dysfunction observed in the NCES "case children." See, *e.g.*, Ex. G (1993 NCES follow-up study report), chapters 3 through 6.

injure a child's brain severely enough to cause the type of chronic dysfunction from which Sierra has suffered, he would expect to see more symptoms in the period immediately following the vaccination than the single seizure that Sierra experienced. He would expect to see a severe "acute encephalopathy," meaning that the child would experience a considerable time period of severely altered mental status, such as unconsciousness, a coma, or changes in the child's interaction with her environment. He would also expect that any changes in the child's developmental ability caused by a vaccine reaction would be obvious in the period *immediately* after the reaction, rather than manifesting themselves months later, as was apparently the case with Sierra.

This argument of Dr. MacDonald certainly has considerable appeal, especially in light of Dr. MacDonald's excellent credentials as an expert in pediatric neurology. However, although the question is a difficult one, I found that this argument of Dr. MacDonald was outweighed by a combination of the contrary testimony of Dr. Bean *and* the heavy weight that I accord to the conclusion of the 1994 IOM Report. Dr. Bean forthrightly acknowledged that the case for vaccine-causation of Sierra's chronic disorder would be *stronger* if she had suffered even more severe symptoms, such as a lengthy loss of consciousness, on the day of her inoculation, or if the failure to reach developmental milestones had been noticed sooner after vaccination than actually was the case. (See, *e.g.*, Tr. 84-85.) However, Dr. Bean, who also has excellent credentials as a pediatric neurologist, argued that nevertheless, in light of Sierra's extended seizure just hours after the vaccination, it is still reasonable to say that Sierra's chronic disorder *probably* was vaccine-caused.

Moreover, the disagreement on this point between Drs. MacDonald and Bean is resolved, in my view, by the fact that the *1994 IOM committee* simply was willing to go further than is Dr. MacDonald in attributing causation of chronic nervous system dysfunction. While Dr. MacDonald would apparently restrict a vaccine-causation finding to situations in which the vaccinee suffered an extended period of *severely altered mental status* very soon after vaccination, the 1994 IOM committee, after evaluating all of the relevant evidence, simply was willing to find vaccine-causation in a slightly wider scope of situations, including situations in which the vaccinee suffered a seizure more than 30 minutes' duration within seven days after vaccination. And the 1994 IOM committee was able to base its conclusion in this regard on *specific evidence* gleaned from the NCES. The fact is that the NCES clearly did find a significantly elevated level of "serious acute neurologic illnesses" occurring within seven days after vaccination, and that category of "serious acute neurologic illnesses" *specifically included* seizures lasting longer than 30 minutes. Dr. MacDonald, on the other hand, *did not* point to any particular study or data in contending that one should accept only situations involving extended periods of altered mental status, and not situations involving extended seizures. Thus, in my view, it is appropriate to accept the conclusion of the 1994 IOM committee, based upon specific NCES data, over the argument of Dr. MacDonald in this regard.[14]

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[14]As noted previously, part of Dr. MacDonald's argument in this regard is that if an infant's brain was substantially damaged by the vaccine, evidence of that damage would inevitably become apparent *immediately*. This argument has some superficial appeal, but I do note that it is somewhat at odds with arguments that pediatric neurologists testifying on behalf of *respondent* have made in

Of course, on this general point the respondent has relied not only upon the testimony of Dr. MacDonald, but also upon a written report designated as respondent's Ex. E (filed Dec. 10, 1998). That report was issued in 1994 by the "Ad Hoc Subcommittee on Childhood Vaccines" sponsored by the National Vaccine Advisory Committee. That Ad Hoc Subcommittee reviewed the 1994 IOM Report, and, in its written report, indicated that it "differed with * * * the IOM findings" as to the topic of "DTP vaccine and chronic encephalopathy." (Ex. E at pp. 3, 6-8.) The subcommittee noted its agreement with the general proposition that with respect to *all* of the "case children" in the NCES who experienced a "serious neurologic event," irrespective of whether that event followed DPT vaccination, there exists a "potential" for the presence of continued neurologic dysfunction ten years later. (Ex. E, pp. 7-8.) But it added that "[h]owever, the data are insufficient to accept or reject whether DTP administration prior to the acute, serious neurologic event influenced the potential for neurologic dysfunction 10 years later." (*Id*. at 8.) Further, the subcommittee's report went on to include the following discussion of the general issue, in a "question and answer" format:

> c. Is there sufficient evidence to change the time interval following DTP vaccine from 3 to 7 days for purposes of the [Table Injury] encephalopathy provision of the VICP?
>
> > The Subcommittee consensus was that there was not sufficient evidence to change the interval for compensation of encephalopathy from 3 to 7 days.
>
> d. Is the NCES working definition of acute neurologic illness consistent with current medical understanding of encephalopathy that can be caused by DTP vaccine?

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many Program cases before me. That is, respondent's neurologists have often opined that neurologic dysfunction discovered in a child shortly after vaccination probably was discovered at that time merely by chance; the dysfunction, they explained, probably was the result of some damage to the brain that occurred months beforehand, during the prenatal period or at birth. Further, in *Almeida v. Secretary of HHS*, No. 96-412V, 1999 WL 1277566 (Fed. Cl. Spec. Mstr. Dec. 20, 1999), the special master quoted testimony from Dr. Marcel Kinsbourne, a pediatric neurologist of excellent credentials, who explained that neurologic damage from a vaccination, like damage from prenatal events, might not be immediately apparent. Dr. Kinsbourne stated that "some damaging events can damage neurons [brain cells] which are as yet not functional, but are programmed to come into action weeks later, months later, years later." 1999 WL 1277566 at *10. Accordingly, in light of the above-described testimony that I and other special masters have heard from neurologists in a number of Program cases, I cannot find that Dr. MacDonald's testimony is sufficiently well-explained to persuade me that brain damage from a vaccination would *inevitably* be immediately apparent. His testimony in this regard, thus, does not persuade me to reject a causation theory based upon the conclusion of the distinguished 1994 IOM committee.

> The Subcommittee emphasized, as did the IOM report, that there is not a distinctive neuropathologic syndrome related to DTP vaccination; rather, it is a theoretical construct. The medical literature related to acute encephalopathy includes febrile seizures. The Subcommittee recognized that the NCES criteria for inclusion into the study cast a very broad net, but that many children who were cases within NCES had been hospitalized with very severe acute disease. There was consensus that the NCES definition of acute neurologic illness was not consistent with current medical understanding of "acute encephalopathy" as an acute, generalized disorder of the brain.

All of these quoted comments seem to indicate that the Ad Hoc Subcommittee generally believed that the 1994 IOM Report had gone too far in its stated conclusion with respect to DPT causation of chronic nervous system dysfunction.

I certainly view the report of the Ad Hoc Subcommittee with great respect and deference. An examination of the make-up of the subcommittee would seem to indicate that its membership have scientific credentials just as impressive as those of the members of the 1994 IOM committee. It is, therefore, a difficult task for me, as a layman, to decide which written report to credit over the other, given that the two committees seem simply to disagree as to how far one can reasonably go in attributing pertussis-vaccine causation of chronic neurologic dysfunction.

My ultimate conclusion, however, is that based upon the record before me at this time, it is reasonable to credit the conclusion of the 1994 IOM committee over the more cautious stance of the Ad Hoc Sub Committee. The chief reason for this is that the reasoning of the 1994 IOM committee is simply better explained, and is based on specific data from the NCES. That is, the 1994 IOM committee carefully explained how its conclusion was based upon *specific evidence* from the NCES. As noted above, the NCES clearly did find a significantly elevated level of "serious acute neurologic illnesses" after DPT vaccination, and that category of "serious acute neurologic illnesses" *specifically included* seizures lasting longer than 30 minutes. The Ad Hoc Subcommittee, on the other hand, made clear that it disagrees with the 1994 IOM committee, but did not clearly explain *the basis* for that disagreement. The Ad Hoc Subcommittee failed to point to any *particular* study or data that caused it to disagree with the 1994 IOM committee. It did not explain in what respect it found deficient the NCES data upon which the 1994 IOM committee relied. In these circumstances, while I respect the views of the Ad Hoc Subcommittee, I cannot, without further explanation, credit those views over the better-explained views of the 1994 IOM committee. I must instead credit the conclusion of the 1994 IOM committee.

Finally, in prior Program cases, the respondent, in opposing causation theories based upon the NCES, has pointed to certain statements made by the authors of that study expressing caution about using the NCES to reach a causation determination in an *individual case*. *See, e.g.*, *Clements v. Secretary of HHS*, *supra*, 1998 WL 481881 at *14-15. Specifically, in the original report of the

NCES in 1981, the authors cautioned that the study's results "should be interpreted with considerable caution." (Ex. F (1981 NCES report) at 98-99.) And when the results of the 1993 NCES follow-up study were published in 1993, the authors, in discussing those results, included comments that "[c]ertainly, attribution of a cause in individual cases must be speculative," and that "[t]he role of pertussis vaccine as a cause or concomitant factor in the aetiology of these illnesses remains unclear and cause cannot be attributed in individual cases."[15]

To be sure, those statements by the NCES authors do, indeed, give me strong reason to pause and be cautious in my current task, which is to attempt to attribute cause to a *particular case* of chronic neurologic dysfunction. But do those statements mandate a conclusion that *no* individual case of chronic neurologic dysfunction can *ever* be reasonably attributed causally to the pertussis vaccine, under *any* standard of proof? After careful consideration of this difficult question, I conclude that to so interpret those statements would be erroneous.

The most important reason for this conclusion is that the statements in question, cautioning generally against attributing causation in individual cases, do not specify the *level of certainty or probability*, in terms of attribution of causation, that the authors had in mind when making the statements. The crucial fact is that the statements were being made in a *medical/scientific journal*, a context in which attribution of causation is typically not made until a level of *very near certainty*--perhaps 95% probability--is achieved.[16] In this context, the statements are not surprising at all. I certainly do not believe that the available evidence justifies *any* conclusions about causation--in general or as to specific cases--at anywhere near that 95% level of *scientific certainty*. But it seems unlikely that the authors of the quoted articles had in mind the *lower standard of probability* necessary in legal proceedings such as this one--*i.e.*, the requirement that causation be shown to be merely "more probable than not." Therefore, I conclude that the above-quoted statements of the NCES authors are *not* inconsistent with my conclusion in this case.[17]

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[15]The researchers who conducted the NCES 10-year follow-up study issued a lengthy formal report describing the study; that report was filed in this case (on Dec. 10, 1998) as respondent's Ex. G, and is entitled *The National Childhood Encephalopathy Study: A 10-Year Follow-up* (MacKeith Press, London 1993). These researchers also published at the same time a shorter article summarizing their findings, which is cited as Miller, Madge, Diamond, Wadsworth, and Ross, *Pertussis immunization and serious acute neurological illnesses in children*, 307 Brit. Med. J. 6913:1171-76 (1993). The two sentences quoted above appeared at page 1175 of the latter article.

[16]See, *e.g.*, Victor Cohn, *News and Numbers* (Iowa St. U. Press, 1989), p. 15.

[17]The cautionary statements quoted above may also indicate the authors' concern that someone might reach a conclusion of vaccine-causation in a particular case based *only* upon the timing of symptoms, without looking at the *overall* circumstances of the case--*i.e.*, without looking to see whether there was some *other* plausible cause involved. That would, of course, be a very reasonable concern. But the "1994 IOM causation theory" takes this concern into account, by providing that the theory should be applied only when the facts of the individual case indicate *no*

In summary, for all the reasons discussed above, I conclude, based upon all the evidence in the record before me, that it is "more probable than not" that Sierra's chronic neurologic disorder, including her seizure disorder, was caused by the DPT vaccination that she received on May 18, 1995.

F. Issue of the "febrile or "afebrile" nature of the initial seizure

One other potential issue that merits a brief discussion concerns the fact that reference to a few of the medical records filed in this case might give the impression that Sierra's initial seizure episode, on the day of the DPT vaccination, might have been an "afebrile" seizure. The term "afebrile" literally means "without fever,"[18] so that the term "afebrile seizure" seems to refer to a seizure that is not accompanied by an above-normal body temperature.[19] Interestingly, in the expert testimony in this case, the experts did *not* focus at all on whether Sierra's initial seizure or additional seizures were febrile (*i.e.*, accompanied by fever) or afebrile. However, I note that two special masters of this court have drawn distinctions between afebrile and febrile seizures, indicating that, based upon certain statements made in the 1991 IOM Report, they might be less likely to find vaccine-causation if the vaccinee's initial seizures were *afebrile*. See *Terran v. Secretary of HHS*, *supra*, 1998 WL 55290 at *10-11; *Salmond v. Secretary of HHS*, No. 91-123V, 1999 WL 778528, at *5-6, 9-10 (Fed. Cl. Spec. Mstr. Sep. 16, 1999).[20]

The simple answer is that in this case, while the record is initially somewhat confusing, careful analysis indicates that Sierra's initial seizure *cannot* be classified as "afebrile." To be sure, in a few medical records, the circumstances surrounding her lengthy seizure on the date of vaccination, May 18, 1995, are described in words that might lead one to believe that her seizure was afebrile. See Ex. 5, p. 96--"[negative] h/o [history of] Fever;" Ex. 5, p. 99--"parents state that there were no * * * fevers preceding event;" Ex. 5, p. 109–"without any fever * * * until [she began shaking];" Ex. 5, p. 110--"no underlying fever." However, other records clearly indicate that Sierra *did* have a fever at the time that she was seizing on May 18, 1995. Most importantly, the records of the first hospital to which she was taken that day, Salem Memorial Hospital, indicate that her temperature at 4:05 p.m. ("1605") was 100.4 degrees Fahrenheit. (Ex. 29, p. 630.) In addition,

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other obvious potential cause.

[18]See, *e.g., Dorland's Illustrated Medical Dictionary* (Saunders and Co., 27th ed. 1988), p. 35; 1991 IOM Report (Ex. C) at p. 88.

[19]The term "fever" means elevation of the body's temperature above normal. *Dorland Illustrated Medical Dictionary* (Saunders & Co., 27th ed. 1988), p. 620.

[20]Another special master, however, recently took a different approach to the issue of whether the DPT vaccine can cause afebrile seizures. In *Almeida v. Secretary of HHS, supra*, the special master expressed disagreement with the distinction made between febrile and afebrile seizures in *Salmond*. See 1999 WL 1277566 at *21, fn. 22.

another record, made months later (apparently based upon the statement of Sierra's parents), states that at the time of her first seizure on May 18, 1995, Sierra "had fever 99." (Ex. 9, p. 178.)

In addition, it is absolutely clear that at the time of her *second* seizure on June 25, 1995, Sierra was suffering from a *very* high fever. See Ex. 7, p. 126--"pt was febrile;" Ex. 7, p. 123--"fever of 40 degrees centigrade" (approximately 104º Fahrenheit). See also the notation later that year that Sierra had been experiencing "seizure disorder triggered by fever high and low." (Ex. 8, p. 176.)

Thus, it is clear that Sierra did have somewhat of a fever with her first seizure, and a very high fever with her second. Therefore, neither her initial seizure, nor her seizure disorder in general, can be said to have been "afebrile."[21]

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[21]I also note that in my view the results in both *Terran* and *Salmond* are absolutely consistent with my own analysis, set forth above, of the available evidence on the *general* issue of whether the pertussis vaccine can cause chronic neurologic injury. That is, as noted above, *Terran* and *Salmond* both involved infants who experienced only *very brief* afebrile seizure episodes during the seven-day period after DPT vaccination. 1998 WL 55290 at *1; 1999 WL 778528 at *1. Neither child suffered a seizure lasting 30 minutes or more, or any of the other acute neurologic symptoms that would have qualified the vaccinee as a "case child" under the NCES. Therefore, under my own analysis set forth above, I would also have denied the claim of the petitioners in *Terran* and *Salmond*, as did the special masters in those cases.

Finally, I add that I do not mean to indicate that I am persuaded that if Sierra's initial seizure or all of her seizures had been *strictly afebrile*, her neurologic disorder would therefore be excludable from the vaccine-caused category. To the contrary, it would seem logical that since any seizure of greater than 30 minutes in duration would fit within the NCES criteria, even in the case of a totally afebrile seizure, the causation theory should be applied. It would seem that the statement of the 1991 IOM report concerning afebrile seizures, upon which the *Terran* and *Salmond* decisions relied, could be interpreted to apply only when there was no seizure of greater than 30 minutes in duration during the seven-day post-vaccination period (as was the case in both *Salmond* and *Terran*). However, I simply need not address such a hypothetical situation in order to decide this case.

G. Final note

I find it appropriate to add a few more concluding thoughts concerning the causation issue, in this case and in general. First and foremost, I stress that the question is a very close one, about which reasonable minds can differ. The evidence that I have examined certainly does not prove *conclusively* that the whole-cell pertussis vaccine ever causes chronic neurologic dysfunction. Indeed, that evidence does demonstrate clearly that *even assuming* that the pertussis vaccine does cause such injury, it does so only on *extremely rare* occasions, perhaps in one in every several hundred thousand or more vaccinations. However, I find that the evidence does justify conclusions that it is at least somewhat "more probable than not" (1) that the pertussis vaccine can cause chronic neurologic dysfunction on rare occasions, and (2) that it did so in Sierra's case.

Finally, I add that it is with considerable caution that I approach the task of ruling upon whether an individual's injury was *actually caused* by a vaccination. I recognize clearly that conclusions of this type, published in a public legal forum, conceivably might contribute to a lack of public confidence in the type of vaccination in question, or even in vaccinations in general. Such a result would be exceedingly unfortunate. The evidence that I have reviewed in this case, and in hundreds of Program cases, shows that the vaccinations commonly given at this time in this country have been fantastic success stories. These vaccinations unquestionably have saved an untold number of lives, and prevented an unmeasurable amount of illness. While a very, very few persons may have been injured by unexpected reactions to such vaccines, there can be no serious question that the benefits of such vaccinations, to both vaccinated individuals and to our society, have outweighed the slight risks involved in a few types of vaccinations. And with respect to the whole-cell pertussis vaccine itself, the evidence also shows absolutely clearly that, even assuming that there is some very slight risk of serious injury, the benefits of vaccination against the pertussis disease, which in the past has killed thousands and sickened millions in this country alone, vastly outweigh any risks involved. Moreover, it is a happy circumstance that the new form of pertussis vaccination now becoming predominant in this country, the acellular vaccine, seems to be a form of immunization that is substantially less prone to causing side effects than was the whole-cell vaccine. Accordingly, I hope that the conclusion of this ruling will be perceived in an appropriate fashion--*i.e.*, with the understand that the scientific evidence is far from clear, and that even assuming that the whole-cell pertussis vaccine does cause chronic neurologic dysfunction, it does so only in exceedingly rare instances.

IV

FURTHER PROCEEDINGS

For the reasons stated above, I find that petitioners are entitled to a Program award on Sierra's behalf. Petitioners' counsel has already been instructed, at the status conference held on

June 23, 2000, to obtain a "life care plan." I will soon schedule a status conference at which to discuss the "damages" issue in this case.

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George L. Hastings, Jr.
Special Master