of tracking long-term dysfunction. This recognition does not provide any information one way or the other regarding causation.

Crucial to understanding the Department's response is the knowledge that the working definition of ''acute neurologic illness'' used in the NCES is not consistent with the current medical understanding of acute encephalopathy as an acute, generalized disorder of the brain. Children were placed in the NCES case definition who experienced only febrile seizures, a benign condition know to be triggered by DTP vaccine, yet never proven to have lasting effects absent signs of acute encephalopathy. Thus, placing seizures in the NCES case definition of encephalopathy is inconsistent with the current medical understanding of acute encephalopathy. Moreover, both the IOM and the NVAC subcommittee agreed that there is no evidence that chronic encephalopathy in the absence of acute post-immunization encephalopathy is causally related to the vaccine. Therefore, there is no basis for providing a legal presumption of vaccine causation for chronic effects based solely on the occurrence of a seizure following DTP immunization. There is simply no need for, nor is there medical evidence to support, a separate presumption for residual seizure disorder in connection with DTP vaccine.

Sudden Infant Death Syndrome

Two commenters suggested there is not a clear distinction between a death characterized as Sudden Infant Death Syndrome (SIDS) and one that is vaccine-related (paragraph (b)(2)(iii) of the NPRM).

The IOM concluded that SIDS is not causally related to DTP vaccine. This conclusion was based on several controlled epidemiologic studies involving hundreds of thousands of vaccinations. Although the diagnosis of SIDS is one of exclusion of other causes, there are specific guidelines as to the history preceding death, findings on forensic examination, and the ruling out of other causes by death scene examination (when possible). Moreover, the possibility that DTP-related deaths are commonly misclassified as SIDS was also considered by the IOM Committee. Since there was no evidence of an increased risk of SIDS following DTP immunization, or of any observable ''pertussis death syndrome,'' the committee considered that such effects were not supported by the medical literature. In addition, those studies that examined infant deaths other than SIDS in relation to DTP vaccine also demonstrated no excess risk in the post-immunization interval. This observation argues against the possibility that DTP-related deaths were missed as a result of their being misclassified as deaths other than SIDS. (Correspondence from Christopher P. Howson, Ph.D., Project Director, Committee to Review the Adverse Consequences of Pertussis and Rubella Vaccines to Dr. George Curlin, Deputy Director, Division of Microbiology and Infectious Diseases, National Institute of Allergy and Infectious Diseases: 9/18/91)

Nevertheless, as with infantile spasms, the Department has decided to remove all references to Sudden Infant Death Syndrome from the final rule. This decision, too, was made based purely on procedural grounds. The Department concluded (as with infantile spasms) that this issue is more appropriately addressed in the ''factor unrelated'' section of the statute (42 U.S.C. § 300aa–13(b)), rather than as part of the Vaccine Injury Table. The decision to make this change does not affect the Department's findings regarding SIDS (based on the IOM report), nor should it be viewed as inconsistent with the above analysis regarding the Department's response to the commenters' concerns. The Department continues to believe that in deciding cases involving SIDS, the Court of Federal Claims should rely heavily on the IOM's conclusion that the evidence does not indicate a causal relationship between pertussis vaccine and SIDS.

Tuberous Sclerosis Complex

One commenter suggested that the proposed revisions do not take into account the condition of tuberous sclerosis complex (TSC), which some believe can be aggravated by DTP vaccine. Since DTP vaccine can cause fevers which trigger seizures, there remains a question whether someone with TSC would have a worse outcome as a result of a seizure following a DTP shot. One commenter suggested that infantile spasms is frequently associated with TSC and the U.S. Court of Federal Claims has found compensable infantile spasms cases that manifested after DTP vaccine. The Department provides the following clarification regarding the effect the new Table will have on individuals with TSC.

TSC is a genetic disorder manifested chiefly as mental deficiency, epilepsy and skin lesions. Seizures occur in 80–90 percent of individuals with tuberous sclerosis. This disorder frequently presents in infancy, commonly in the form of infantile spasms. Some petitioners have argued that administration of a DTP vaccine can significantly aggravate a case of TSC.

The Act provides two avenues of proof in order to establish eligibility for compensation. A petitioner is afforded a presumption of causation if he/she can establish that an injury listed in the Table occurred within the specified time period. Otherwise, the petitioner may argue that an injury occurred which is not listed in the Table, but which was nonetheless caused by the vaccine. The TSC cases presented to the Court, some petitioners who sought to establish a Table case argued that the child experienced seizures within 3 days of receipt of a vaccine and that this event significantly aggravated the pre-existing TSC. Some petitioners who were unable to establish Table cases argued that although the child did not sustain an injury listed in the Vaccine Injury Table, the vaccine nonetheless was the cause-in-fact of the aggravation of the underlying Tuberous Sclerosis. In either case, the petitioner had the burden of proving that the clinical course of the pre-existing condition had been significantly aggravated. Typically, petitioners presented expert testimony to support this theory.

The revisions to the Vaccine Injury Table do not, by and large, change the petitioner's burden of proof in TSC cases. The only difference is that there is not a presumption of causation for residual seizure disorders for DTP vaccine. As explained in the preamble to the NPRM, and reiterated here, the IOM concluded that there is no causal relation between pertussis vaccine and afebrile seizures. However, to receive a presumption of causation, petitioners may still argue that an encephalopathy (as defined in the revised Qualifications) occurred within 3 days of vaccine administration and that this encephalopathy significantly aggravated the pre-existing Tuberous Sclerosis. In addition, petitioners may continue to argue that the vaccine was the cause-in-fact of the aggravation of the TSC. As far as infantile spasms is concerned, the Department has removed all references to this condition from the final rule as explained above. Therefore, petitioners have available to them the same avenues of proof open to individuals with other types of seizures.

One commenter noted that MMR frequently triggers epilepsy in children with TSC. The same analysis as above applies. Here, the petitioner may take advantage of the presumption of causation if he or she is able to prove either a Table encephalopathy, or a Table residual seizure disorder, and that that injury significantly aggravated the underlying TSC. If the evidence does