months of residual effects, and who experience chronic neurological dysfunction. This presumption is consistent with the IOM's conclusions articulated in its 1994 report.

Four commenters suggested that the IOM's causation category of ''insufficient evidence'' should not be interpreted to mean that DTP vaccine does not cause the condition. Furthermore, they suggest that both the IOM and the Department present no data which support the proposition that acute encephalopathy, subsequent to the receipt of a pertussis vaccine, has a more benign neurological outcome than acute encephalopathies from other agents. The Department has considered these comments but maintains that the IOM report provides a foundational basis for the proposed changes.

The 1991 IOM report concluded the evidence was insufficient to indicate a causal relationship between vaccines containing pertussis and chronic neurological damage for a variety of conditions including encephalopthy, shock collapse or Hypotonic-Hyporesponsive Episode (HHE), epilepsy, and other neurologic and non-neurologic disorders. Comments that expressed concern over this classification focused for the most part on acute encephalopathy and chronic neurologic damage, while a few discussed shock-collapse (HHE) or recurrent seizures (epilepsy). The issue of encephalopathy following pertussis vaccination is a difficult one. On one hand, in its 1991 Report, the TOM found evidence ''consistent with a familiar evidence ''consistent with a causal relation'' for acute encephalopathy, yet on the other hand, it decided there was ''insufficient evidence'' regarding *chronic* nuerologic damage. Due to limitations in the data, the IOM could not conclude with any certainty whether there is any causal relationship between pertussis vaccine and shock-collapse (HHE), epilepsy, or any of the other disorders under this classification category. In its 1994 report addressing the Miller study, the IOM concluded that ''evidence is insufficient to indicate whether or not DTP increases the overall risk in shildren of chronic nervous system dysfunction.'' They concluded further, that the ''balance of evidence is consistent with a causal relation between DTP and the forms of chronic nervous system dysfunction described in the NCES in those children who experienced a serious acute neurological illness within 7 days after vaccine administration.'' The IOM also concluded, however, that ''the evidence remains insufficient to indicate the presence or absence of a causal relation between DTP and chronic nervous system dysfunction under any other circumstances.'' *See* 1994 IOM Report, Executive Summary.

Because section 2111(c) of the Act requires that a Petitioner must show 6 months of residentual effects of a Table injury, a finding of a relation pertussis-containing vaccines and acute, but not chronically, does not justify the presumption of causation for long-term neurologic damage. However, should the evidence show that abnormal neurologic signs continued beyond the acute state, and therefore the injured indidivual never returned to a ''normal neurological state,'' than title may be granted. This conclusion is consistent with the 1994 IOM report.

The language of section 312 of Pub. L. 99–660 (42 U.S.C. 300aa–1, note) also supports the Department's conclusion. The IOM determined in its 1991 report that the evidence is insufficient to support a conclusion that a causal relationship between DTP vaccine and chronic neurologic damage exists. The 1994 IOM finding was limited to the conditions described in the NCES and to those children who experienced an acute event following vaccination. Therefore, the Department concluded that it could not ''reasonably determine'' that as a general rule a causal relationship exists, and the Table is being modified accordingly. Because section 312 requires such a determination in order to sustain the presumption of causation, the Department was obligated to revise the Table consistent with the conclusions of the IOM.

The removal of the legal presumption of causation has been applied to other conditions in the ''insufficient evidence'' category (i.e., HHE and residual seizure disorder). The Department notes, however, that the removal of a condition from the Table, or the inclusion of a revised definition thereof, will not necessarily result in compensation being denied where it would have previously been awarded. Petitioners may still prevail by providing proof that the vaccine actually caused the specific injury alleged to have occurred.

Three commenters suggested that the IOM's burden of proof standard was too high. They suggested that the IOM should develop a confidence level that is more lenient than 95 percent, particularly when it is applied to the ''preponderance of the evidence'' burden of proof standards present in the VICP. After consideration of the process used by the IOM in developing its report, it is the Department's view that the IOM's standard was appropriate.

Congress mandated that the IOM review the scientific literature and other information on specific adverse consequences of pertussis and rubella vaccines. The Committee was composed entirely of physicians and scientists, whose task it was to evaluate the literature on adverse events following these vaccines. Any ''burden of proof'' standard had to be consistent with the standard applied throughout the science of epidemiology, policy considerations notwithstanding. It is the Secretary's responsibility under section 312 of Pub. L. 99–660 (42 U.S.C. 300aa–1, note) to utilize the IOM's conclusions to provide a better scientific rationale for any presumptions of vaccine causation under the Program.

Moreover, although the statute requires merely a ''preponderance of the evidence'' standard in evaluating compensation claims, there is no requirement that anything other than the standard commonly used among scientific and medical professionals be applied in re-defining those conditions which will receive a presumption of causation by use of the Table. The preponderance of evidence standard is only relevant when a Master is evaluating a particular case.

One commenter suggested that the IOM conclusions were incorrect regarding DTP's pathological effects in animals or children. The commenter stated that the IOM erred in diminishing the importance of, or incorrectly judged, the conclusions of controlled epidemiologic studies. Furthermore, the commenter suggested that the IOM Committee was remiss in its examination of the evidence concerning long-term sequelae for HHE. Finally, two commenters criticized the IOM because no original research was done in putting together its conclusions. As stated above, the Department has considered these comments, but has determined that the process used by the IOM was appropriate.

The 1991 IOM Committee was made up of 11 experts in infectious disease, pediatrics, internal medicine, neurology, epidemiology, biostatistics, decision analysis, immunology and public health. During the 20 months of their work, approximately 1,400 citations were reviewed and 5 public meetings were held. No new research was conducted. Committee members considered new or controversial data and various points of view and sought to identify gaps in knowledge. The IOM cited many gaps and limitations of knowledge. Its conclusions were reached, however, after an exhaustive analysis of the best epidemiologic data available, and other information.