

In the Department's view, the original statute does not intend the Special Master to find that the injury occurred within the Table period in the absence of any records recording the injury, unless the petitioner is able to produce clear, cogent, and consistent testimony to explain the absence of records. The Court has found in favor of petitioners in the absence of corroborating medical records where the preponderance of evidence, including oral testimony, demonstrates that the adverse event occurred within the Table timeframe. The requirement contained within the revised Aids to Interpretation is meant to include only those events which are so serious that they require medical intervention (whether or not medical intervention was actually sought), and are, therefore, properly referred to as encephalopathies. The requirement is simply meant to exclude those conditions which are not serious enough to warrant medical attention. These types of minor symptoms (e.g., excessive crying, sleepiness) were specifically excluded from the definition of encephalopathy contained within the original statute, but have been alleged by some petitioners to be signs and symptoms of an encephalopathy. The revised Qualifications and Aids to Interpretation simply seek to make clear the intent of Congress.

The Department recognizes, however, that the language "should be sufficiently severe," is somewhat confusing. In addition, the Department recognizes that the phrase "medical intervention and hospitalization" is redundant, and open to various interpretations. Accordingly, the regulatory language in § 100.3(b)(2)(i) as proposed has been revised to read "An acute encephalopathy is one that is sufficiently severe so as to require hospitalization." The Department is making this change in the interests of clarity, consistent with the explanation articulated above. In order to demonstrate a Table encephalopathy, the petitioner must prove that the injury was indeed serious enough to warrant hospitalization, whether or not records of such hospitalization exist. Certainly, however, contemporaneous medical records are of extreme importance in proving that a Table injury occurred.

#### *The Sufficiency of the IOM Report as the Basis for the Changes to the Vaccine Injury Table*

Several commenters stated that the Department relied on insufficient data in proposing modifications to the Table. These commenters argued that Congress intended that more definitive

information be available before the Table is revised. The commenters took issue with both the conclusions of the Institute of Medicine and the Department's interpretation of those conclusions. Section 312 of Pub. L. 99-660 (42 U.S.C. 300aa-1, note) required the Secretary to complete a review of "all relevant medical and scientific information regarding the connection between various vaccines and specified adverse events." The Secretary was then required to publish in the **Federal Register** findings regarding "whether each of the illnesses or conditions set forth in subsection (a) can reasonably be determined in some circumstances to be caused or significantly aggravated by pertussis containing vaccines." See 42 U.S.C. 300aa-1, note. Simultaneously, the statute required that the Secretary propose changes to the Table as a result of the findings.

This language indicates that Congress intended that the Secretary modify the Table consistent with the conclusions of the review undertaken by the Institute of Medicine. Nowhere is there a requirement, however, that the causal connection between the administration of vaccines and certain adverse events be definite and conclusive before any changes are made. The IOM concluded that "the evidence is insufficient to indicate a causal relation between vaccines containing pertussis" and certain adverse events. Because the evidence was determined as "insufficient," the Department concluded that it could not "reasonably determine" that a causal connection exists, and the Table is being revised accordingly.

The section of the legislative history cited by the commenter in support of the objection states that "the Committee anticipates that the research on vaccine injury and vaccine safety now ongoing and mandated by this legislation will soon provide more definitive information about the incidence of vaccine injury and that, when such information is available, the Secretary or the Advisory Commission on Childhood Vaccines (discussed below in section 2119) may propose to revise the Table as provided below in section 2114." This statement merely indicates a recognition by Congress that the original Vaccine Injury Table was overinclusive, and that more research would yield more definitive information. As described in the preamble to the proposed regulation, and consistent with the statutory requirements, the findings of the Institute of Medicine represented a comprehensive review of the existing evidence as well as numerous opportunities for comment

from various experts and members of the public. The systematic process undertaken by the Department to evaluate the findings of the IOM demonstrates that the Department reviewed sufficiently the findings of the IOM and their applicability to the Table. These findings clearly indicated that the original Table was out of step with the state of medical knowledge.

Accordingly, the Secretary was obliged to propose revisions. Although the IOM's original conclusion was modified somewhat in the 1994 report regarding pertussis vaccine and chronic nervous system damage, the Department has determined that the major changes to the Table published in the NPRM reflect the IOM's latest conclusions regarding this difficult issue. Nevertheless, as discussed below, the final rule reflects some minor changes made to the proposed rule in light of the Miller study and comments provided to the Department in connection with this study.

Two commenters felt that the Department had ignored relevant information in revising the Table. Specifically, they believed that the Department should have viewed the claims that have either been compensated or conceded by the Department as proof that the presumptions conferred by the Table are accurate. However, the fact that a particular case has either been adjudicated compensable or conceded by HHS does not imply that a medical conclusion regarding vaccine-relatedness has been made. The process of deciding claims is based on whether the claim fits the parameters of the Table, or whether causation has been proven. Most claims have been adjudicated "table cases," meaning that the petitioners were afforded the presumption of causation conferred by the statute. This determination involves an analysis of various evidentiary and other legal issues, but does not prove or disprove whether a causal relationship exists in fact between certain vaccines and adverse events. The outcome of these cases does not have any bearing on whether the Table should be revised to reflect the findings of the Institute of Medicine.

One commenter referred to a letter written by the organization Dissatisfied Parents Together on May 8, 1991, to then Secretary Sullivan regarding concerns that members of the Immunization Practices Advisory Committee (ACIP) who have advised pharmaceutical companies, or conducted research funded by such companies may have a conflict of interest which precludes their serving