not demonstrate that the case meets the requirements of the Table, the case will be evaluated based on a causation theory.

Diphtheria/Tetanus Vaccines (DT, TD, TT)

One commenter suggested that making changes to non-pertussis components based on studies of pertussis vaccine is inappropriate.

Although the section 312 study (''IOM Report'') did not specifically study the non-pertussis antigens of DTP vaccine (i.e., diphtheria, tetanus), most individuals receiving pertussis antigen, also were given these antigens. Therefore, some inferential data is present. Moreover, studies reveal little evidence that these antigens are causally related to the injuries currently listed in the Table under DTP, other than Anaphylaxis. In the section 313 study, the IOM concluded that the evidence favored rejection of a causal relation between DT/Td/TT and encephalopathy. After review of the section 313 Report, the Department may promulgate additional changes to the Table.

MMR Vaccines

One commenter suggested that the requirement for at least 5 days of viral replication is inappropriate. One commenter suggested that the changes for encephalopathy are wrong because there is a broad spectrum of severity. Sequelae may occur after less serious acute encephalopathy. The proposed changes would exclude all but the most severe acute encephalopathies from the Table. The Department has considered these comments, but has concluded that the medical evidence supports the proposed changes.

Since viral replication is required for a viral vaccine-associated encephalopathy, a window for the expected time of onset is appropriate. The onset of vaccine-related illness following MMR (or any of its components) is generally from 7 to 14 days, thus a time interval of 5 to 15 days would be all-inclusive. Any acute encephalopathy of unknown cause, regardless of severity or duration, that occurs during the 5 to 15 day time frame would be eligible for the Table presumption, provided the child or adult has continued evidence of ''chronic encephalopathy.'' The 1991 NVAC Subcommittee felt there was strong support in the literature to narrow the timeframe as above. Some felt Residual Seizure Disorder should be removed from the Table based on the lack of evidence for causation in the current medical literature. This was not done because it went significantly beyond the scope of changes proposed by the PHS Task Force. However, at that time, the Subcommittee recognized additional changes may be forthcoming once the section 313 study results are published and have been reviewed. Since the Subcommittee's original discussion on this issue, the IOM issued its section 313 report. The IOM concluded for both encephalopathy and residual seizure disorder that the evidence is inadequate to accept or reject a causal relation. After review of the 313 Report, the Department may promulgate additional changes to the Table based on this conclusion.

One commenter suggested that the evidence for an association between rubella vaccine and chronic arthritis is inconclusive. The section 312 IOM Committee concluded that the evidence is ''consistent with a causal relation'' between the currently used rubella vaccine (RA 27/3) and chronic arthritis in adult women, although the evidence is limited in scope and confined to reports from one institution. To establish this biologically plausible relation more firmly, the Committee expressed the need for prospective, double-blind, controlled trials in which individuals are followed for at least 12 months after vaccination with attempts to isolate and identify rubella virus. At least one medical research center is pursuing this research to try and obtain better data on causation.

Many investigators still view the evidence as inconclusive with regard to chronic arthritis. However, the IOM's finding justifies the inclusion of chronic arthritis on the Vaccine Injury Table since there is biologic plausibility of causation, and the term ''chronic arthritis'' is defined as effects lasting greater than 6 months. In this instance, the IOM is stating there is ''consistent'' evidence for both acute onset and residual effects lasting greater than 6 months. Previously described changes for Table injuries under DTP involved conditions (i.e., HHE and Residual Seizure Disorder) that the IOM did not view as having strong evidence for *both* acute and chronic effects.

Although the Department added chronic arthritis to the Table, guidelines written into the Aids to Interpretation will preclude patients with pre-existing conditions or other non-vaccine related musculoskeletal disorders from being legally presumed to have a vaccine-related injury. As information from prospective studies becomes available, modifications may be made to the Table or Aids to Interpretation based on this data.

Polio Vaccines

Two commenters suggested that Inactivated Polio Vaccine (IPV), known as the Salk vaccine, may be proven to be causally related to poliomyelitis. The IOM evaluated the relationship between polio vaccines and adverse events in its section 313 study. Except for the 1955 incident with inadequate inactivation of live polio virus in the Cutter Company supply of IPV, there have been no serious adverse events causally tied to this vaccine. Since the ''Cutter Incident,'' when manufacturing and testing difficulties were identified and corrected, the safety of released inactivated Poliovirus vaccine has been assured. (See IOM Section 313 Report at 188,; *see also* Bodian, D., et al. Interim Report, Public Health Service Technical Committee on Poliomyelitis Vaccine. JAMA:1444–7, 1955) Furthermore, no serious side effects of currently available inactivated poliovirus vaccines have been documented. (Report of the Committee on Infectious Diseases, American Academy of Pediatrics 1991:389) Because these earlier problems have been cured, and there is no current evidence bearing on a causal relationship, the section 313 study does not discuss specifically the connection between IPV and poliomyelitis. Therefore, there is no evidence of a causal relationship which would justify adding poliomyelitis to the Table for IPV.

Other Changes

At the meeting on June 1–2, 1994, members of the ACCV suggested that the definition of ''sequela'' imposes a higher burden of proof than that required by the statute. The Department disagrees that the definition affects the burden of proof, but agrees that the definition as written should be simplified. Accordingly, the definition in § 100.3(b)(5) has been modified to read as follows: ''The term sequela means a condition or event which was actually caused by a condition listed in the Vaccine Injury Table.'' This definition is consistent with current scientific understanding that in order for a subsequent event to be considered a sequela of an initial event, there must be a causal relationship between the two.

Technical Changes

First, in publishing the NPRM, the Department inadvertently misquoted the statutory introduction to the Vaccine Injury Table. Accordingly, the introductory paragraph of § 100.3(a) now reads as follows: ''In accordance with section 312(b) of the National Childhood Vaccine Injury Act of 1986,