on the ACIP. The Department has determined that this comment is irrelevant as far as the modification of the Table is concerned. In undertaking its review, the IOM did not rely on the views of members of the ACIP or the work-product of that Committee.

The Effect of the Proposed Changes on the Vaccine Injury Compensation Program

Two commenters suggested that the result of the proposed revisions would be an increase in the transaction costs of the Program because many petitioners will pursue their cases by attempting to prove causation-in-fact. The Department has taken this concern into consideration and has concluded that the benefits of the proposed regulation outweigh the possibility of more protracted and complex hearings. The intent of the regulation is to make the Table consistent with medical knowledge regarding the relationship between vaccines and certain adverse events. The Department notes that Congress recognized that the original Vaccine Injury Table would permit individuals whose conditions were not related to vaccine administration to be adjudicated eligible for compensation. If the Table is revised to permit compensation only in those cases where vaccine relatedness is more accurately proven, greater resources will be available to compensate those truly deserving of compensation.

In a similar vein, several commenters expressed concern that the Department was seeking to prevent children deserving of compensation from receiving assistance under the Program. In fact, exactly the opposite is true. The revised Table merely affects the presumption of causation available to certain petitioners. Petitioners will, of course, continue to have the option of proving causation by a preponderance of evidence if they are unable to prove a Table injury. Moreover, the Department recognizes that there is a desperate need for parents to obtain resources to cover the significant medical costs of caring for a sick child. However, the intent of the VICP was to compensate only those individuals whose injuries are vaccine-related. The proposed regulation is simply an attempt to come closer to realizing this goal than was possible with the language of the original Vaccine Injury Table.

Three commenters suggested that the proposed regulation would result in an increased number of civil actions filed against vaccine manufacturers and administrators. In enacting the National Childhood Vaccine Injury Act, Congress determined that one of the goals of the Act was to reduce the number of civil actions filed against vaccine administrators and manufacturers. The other major goal was to provide compensation to those individuals whose conditions were caused by vaccines. *See* H.R. Rept. 99–908, Part 1, September 26, 1986, page 6 (reprinted in 1986 U.S. Code Cong. & Admin News, Vol. 6, page 6347). The Committee recognized, however, that the Table would possibly provide compensation to some children whose illnesses are not vaccine-related, but that further research and modifications to the Table would result in a more equitable distribution of funds. In balancing these two Congressional goals, the Department has determined that the benefits of fulfilling the latter requirement outweigh the risk that an increased number of civil actions will be filed against vaccine administrators or manufacturers.

Furthermore, the Department believes that the combined effect of the IOM's review and this regulatory action may reduce the extent of tort litigation by giving the courts (and potential plaintiffs weighing the wisdom of filing suit) definitive guidance as to the state of scientific knowledge regarding vaccine-related injuries. As causation must typically be proven in tort actions, the Department believes that the findings on these issues may well reduce the amount of tort litigation and may allow easier resolution of any such claims that are litigated.

II. Medical Issues

The Department's Interpretation of the IOM Report

Six commenters suggested that the Department's findings are a misinterpretation of the IOM Report. In the Department's view, however, the proposed changes do reflect accurately the conclusions of the IOM report.

Both the NPRM and the final rule (with some revisions are discussed below), reflect most closely the package of recommendations as developed by the PHS Task Force, reviewed by the NVAC, and endorsed by the ACCV. The proposed changes are in accordance with the scientific findings of the IOM Committee. In instances where the IOM found information suggesting a causal relation *and* continued effects, the Department acted to ensure coverage under the Program (e.g., adding chronic arthritis to the Table). However, where the IOM found that the evidence did not support a causal relation and continued effects, the Department removed the legal presumption of causation by removing or redefining the current injury listed on the Table. The fact that the proposed revisions received overwhelming approval from three independent science and health policy committees, and the endorsement of two national health professionals associations (American Academy of Pediatrics and American Medical Association), confirms the basic soundness of the initial proposed revisions.

One of the commenters addressing the Miller study suggested that in light of the 1994 IOM Report, the Department should rescind certain findings made after release of the 1991 Report and published in the preamble to the NPRM. In the NPRM, published on August 14, 1992, the Department made certain findings as required by section 312(b) of Pub. L. 99–660 (42 U.S.C. 300aa–1 note). The Department has reviewed these findings again in light of the commenter's concerns, and has determined that the findings remain valid. In fact, the conclusions of the IOM and the NVAC subcommittee (discussed below) with respect to pertussis vaccine and chronic neurological damage confirm the soundness of findings three and four as listed in the NPRM. These findings read, in pertinent part, as follows:

> 3. The evidence is insufficient to indicate a causal relation between vaccines containing pertussis and: Epilepsy * * * chronic neurologic damage, * * * learning disabilities and attention-deficient disorder, * * * or permanent neurologic damage or death following hypotonic-hyporesponsive episodes.
>
> 4. The evidence is consistent with a causal relation between vaccines containing pertussis and? Acute encephalopathy and shock and ''unusual shock-like state.''

The recent IOM report was confined to a review of the Miller study, and is, therefore, limited to the circumstances of that particular study. Given the conclusions articulated by the IOM and the accompanying caveats, and the discussion and conclusions of the NVAC subcommittee, the Department concludes that the findings published with the NPRM reflect best the state of scientific knowledge. It should be noted again that in drafting the revised Qualifications and Aids to Interpretation, the Department decided not to eliminate the presumption of causation for encephalopathy despite the conclusions of the 1991 IOM study. Rather, consistent with the recommendation of the ACCV, the Department included a presumption of vaccine causation for those individuals who experience an acute encephalopathy within 3 days after vaccination, who go on to suffer 6