

and conditions can reasonably be determined to be caused by certain vaccines. It further requires the Secretary to make findings regarding "the circumstances under which such causation or aggravation can reasonably be determined to occur." 42 U.S.C. 300aa-1 note. The purpose of the Qualifications and Aids to Interpretation is to describe those circumstances under which certain conditions occur. Congress stated that the Qualifications provide "various descriptions and definitions that the Committee intends be used in interpreting the meaning of the Table." See H.R. Rept. 99-908, Part 1, September 26, 1986, page 19 (reprinted in 1986 U.S. Code Cong. and Admin. News, Vol. 6, page 6360). Given that Congress required the Secretary to make findings regarding the circumstances under which causation can occur, and that she was then required to promulgate regulations as a result of such findings, she could not have fulfilled her obligations under section 312 without modifying the Qualifications as well as the Table itself.

Moreover, the statutory language and the legislative history quoted above indicate that the Qualifications must be viewed as part of the Table. The statute states that "the following qualifications and aids to interpretation shall apply to the Vaccine Injury Table in subsection (a)." See 42 U.S.C. 300aa-14(b). Thus, Congress intended the Table and the Qualifications to be viewed as one unit because the Qualifications explain and clarify the terms of the Table. It stands to reason, therefore, that if the Table is changed, the Qualifications must be changed accordingly.

In fact, Congress anticipated that changes to the Table would require similar changes to the Qualifications and Aids to Interpretation in order to guarantee that the two sections are consistent. The statute states that "if a provision of the table to which paragraph (1), (2), (3), or (4) [the paragraphs of the Qualifications and Aids to Interpretation] applies is revised under subsection (c) or (d), such paragraph shall not apply to such provision after the effective date of the revision unless the revision specifies that such paragraph is to continue to apply." (42 U.S.C. 300aa-14(b)(4)). Thus, the Qualifications contained in the original statute become null and void once that initial Table is changed, unless the Secretary specifies that they are to apply. Implicit in this authority is the authority to promulgate by regulation Qualifications applicable to the revised Table.

Two commenters stated that the regulation exceeded the Department's authority by attempting to prescribe elements of proof necessary to prevail in a petition for vaccine compensation. They argued that this function is reserved to the United States Court of Federal Claims. As explained above, the Secretary is authorized to revise the Qualifications as well as the Table. The statute states that the Secretary may "add to, or delete from, the list of injuries, conditions, and deaths for which compensation may be provided or may change the time periods for the first symptom or manifestation of the onset or the significant aggravation of any such injury, disability, illness, condition or death." The original Table and Qualifications delineate those elements which must be proven in order to take advantage of a presumption of causation.

In this regard, the commenters should understand the function of the Table. The purpose is not to set forth standards of proof for establishing causation-in-fact. Rather, the purpose is to set out a standard for establishing presumed causation, which, absent a finding of a factor unrelated to the vaccine, will allow a petitioner to receive compensation without the burden of proving causation for those conditions included on the Table. Accordingly, the Qualifications properly set out standards for defining those conditions on the Table. Petitioners remain free to establish causation in fact by producing credible scientific information peculiar to their conditions.

Although the commenters assert that the Department is impermissibly creating elements of proof, the Qualifications as drafted originally contain numerous requirements that are, in essence, elements of proof. For example, the paragraph describing the requirements for a 'residual seizure disorder' states the number of seizures which must have occurred in the year after the vaccine was administered for the petitioner to be found to have suffered a residual seizure disorder. In addition, section 2114(b)(3)(A) of the Act describing the definition of encephalopathy states that "Encephalopathy usually can be documented by slow wave activity on an electroencephalogram." Similarly, the revised Qualifications indicate the elements which must be proven to establish a presumption of causation for those injuries and conditions listed in the modified Table.

In objecting to this aspect of the Qualifications, the commenters assume erroneously that the revised Qualifications alter the Special Master's

role in determining whether a Table Injury has been proven. The Special Master's role is to consider the information contained in the record, including oral testimony, medical records and medical opinion. The Master must weigh the evidence, examine the credibility of the witnesses, reconcile the points of disagreement between the parties and issue a final decision. The revised Qualifications do not alter this role. As did the former Qualifications, they require the petitioner to demonstrate a Table condition by proving that various events occurred. The Special Master must still analyze the evidentiary issues which arise in the context of attempting to prove a Table injury.

The Effect of the Regulation on Other Statutory Sections

One commenter stated that the Qualifications and Aids to Interpretation are inconsistent with section 2113(b) of the Act, which permits the Special Master to find that the injury occurred within the Table period even if the symptoms were not recorded or were incorrectly recorded in the medical records. The commenter specifically took issue with the section of the revised Qualifications which states that an "an acute encephalopathy should be sufficiently severe to require health care intervention and hospitalization." In addition, during the June 1994 meeting of the ACCV, at least one member of the Commission objected to this requirement as being overly restrictive because hospitalization is required. The Commission member voicing this concern felt that the rule should recognize that not all parents would respond to a possible encephalopathic event by taking the child to the hospital.

The revised Qualifications and Aids to Interpretation are not inconsistent with section 2113(b) of the Act, because the Special Master may still find that a preponderance of the evidence indicates that the encephalopathy was severe enough to require medical intervention or hospitalization, but that because of error or omission the event was either not recorded or was incorrectly recorded. In addition, under the revised Qualifications, although medical records should be provided in most cases, the language "sufficiently severe" is meant to be consistent with section 2113(b)(2) of the Act and would permit a finding in favor of petitioner if the Special Master found that a preponderance of the evidence indicated that the injury was sufficiently severe such that medical intervention should have been sought.