Updating the Vaccine Injury Table: Legal and Policy Considerations

Elizabeth H. Saindon
Senior Attorney
Office of the General Counsel, HHS

Entitlement to Compensation

- To be compensated, need to demonstrate one of the following:
  - proof of a Vaccine Injury Table condition (unless respondent demonstrates cause was factor unrelated)
  - proof of causation by preponderance of the evidence
  - proof of significant aggravation of Table or off-Table injury

Entitlement to Compensation

- Must show residual effects
  - Died from administration of the vaccine; or
  - Required inpatient hospitalization and surgery as result of vaccine-related injury; or
  - Suffered residual effects/complications of vaccine-related injury for more than 6 months after vaccine's administration.

Vaccine Injury Table

- To qualify as a Table Injury, Petitioner must demonstrate:
  - Received a vaccine set forth in the Table
  - Sustained, or had significantly aggravated, any illness, disability, injury or condition set forth in the Table in association with the vaccine received, or died from the administration of the vaccine
  - First symptom or manifestation of the onset or of the significant aggravation of any such illness, disability, injury, or condition or the death occurred within the time period after vaccine administration set forth in the Table

42 U.S.C. § 300aa-11(c)(1)

Vaccine Injury Table

- "Qualifications and Aids to Interpretation" (QAI) define the injuries listed on the Table
  - "The following qualifications and aids to interpretation shall apply to the Vaccine Injury Table"

42 U.S.C. § 300aa-14(b), 42 C.F.R. § 100.3(b)

Regulatory Table Revisions

- The Secretary may modify the Table by promulgating regulations
  - Add to or delete from the list of injuries, disabilities, illnesses, conditions, and deaths for which compensation may be provided
  - May change the time periods for the first symptom or manifestation of the onset or the significant aggravation of any Table injury or death

42 U.S.C. § 300aa-14(c)

- Regulatory table found at 42 C.F.R. § 100.3(a)

Regulatory Table Revisions

- Any modification of the Table shall apply only with respect to petitions for compensation filed after the effective date of the regulation.

  42 U.S.C. § 300aa-14(c)(4)

Regulatory Table Revisions

- Secretary may not propose a regulation to modify the Table unless
  - Secretary has first provided to the Advisory Commission on Childhood Vaccines (ACCV) a copy of the proposed regulation
  - Requested recommendations and comments by the ACCV
  - Afforded the ACCV at least 90 days to make such recommendations.

42 U.S.C. § 300aa-14(c)

Regulatory Table Revisions

- Statutory standard for adding vaccines:
  - When CDC recommends a vaccine for routine administration to children, the Secretary shall, within 2 years, amend Table to include such recommended vaccine

  42 U.S.C. § 300aa-14(e)(2)

- No statutory standard for adding or removing injuries.

ACCV Guiding Principles

- In 2006, the ACCV developed “Guiding Principles” for recommending revisions to the Table.
- The Table should be scientifically and medically credible
- Where there is credible scientific and medical evidence both to support and to reject a proposed change to the Table, the change should, whenever possible, be made to the benefit of petitioners

ACCV Guiding Principles

- Guidelines for what is “scientifically and medically credible”
  - If IOM study: conclusions of the IOM should be deemed credible but should not limit the deliberations of the ACCV.
  - For data sources other than IOM report, assess the relative strength. Also assess consistency if there is no IOM report. Consistency across multiple sources of evidence is an indication of credibility.

ACCV Guiding Principles

- Hierarchy of data sources (strongest to weakest)
  - Clinical laboratory data
  - Challenge/re-challenge data involving non-relapsing symptoms or diseases
  - Controlled clinical trials
  - Controlled observational studies (e.g., cohort and case control studies), including but not limited to studies based upon data from the Vaccine Safety Datalink (VSD) database
  - Uncontrolled observational studies (e.g., ecological studies)
  - Case series
  - Data from passive surveillance systems, including but not limited to the Vaccine Adverse Event Reporting System (VAERS)
  - Case reports
  - Editorial articles on scientific presentations
  - Non-peer reviewed publications

ACCV Guiding Principles

- Additional factors that affect the relative strength of evidence (*e.g.*):
  - Methodological limitations
  - Potential bias
  - Potential confounding factors
  - Biologic coherence

- ACCV should request assistance from Division of Vaccine Injury Compensation in assessing the relative strength of evidence.

ACCV Guiding Principles

- Remain aware of policy considerations underlying the Table.
  - Awards to vaccine-injured persons are to be made quickly, easily, and with certainty and generosity.
  - Congress intended to compensate serious injuries
- If there is a split in credible scientific evidence, ACCV members should tend toward adding or retaining the proposed injury.