Update on the National Vaccine Injury Compensation Program (VICP)

National Vaccine Advisory Comimittee
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National Childhood Vaccine Injury Act (NCVIA) of 1986

- Federal level "no-fault" compensation system
- Simplified, streamlined approach to litigation
  - table of compensable injuries
  - rules of evidence, discovery and other legal procedures relaxed to accelerate process
- Must file first with the federal system
- Must reject judgment to sue vaccine company and/or healthcare provider
- No age restrictions on who may file

Administrative Entities

- Department of Health and Human Services
  - administers program (claims review/payments)
  - develops recommendation +/- entitlement to compensation
- Department of Justice
  - represents HHS in court
- US Court of Federal Claims
  - final decision maker (special masters)
    - entitlement *and* damages

Eligibility to File

- Statute of Limitations
  - *36 months* from date of occurrence of first symptom or manifestation of onset or of significant aggravation of injury
  - *24 months* from date of death, but no more than *48 months* after date of occurrence of first symptom or manifestation of onset or of significant aggravation of injury from which death resulted
  - If Table is revised (e.g., vaccine or injury added), 2 years from date of revision if injury occurred within 8 years before revision (past injuries)

Entitlement Determination

- To be compensated, one must demonstrate one of the following:
  - proof of a Vaccine Injury Table condition
    - unless factor unrelated present
  - proof of causation
  - proof of significant aggravation
- Standard of proof (civil standard) -- preponderance of evidence (more likely than not)
- Effects of injury must:
  - last greater than 6 months, or
  - have resulted in inpatient hospitalization AND surgical intervention

Awards

- Injury--usually initial lump sum and annuity
  - annuity pays lifetime stream of benefits
  - pain and suffering (non-economic) capped at $250K
  - unlimited lost wages/attorneys fees/costs
- Death--lump sum limited to $250,000
- Attorneys' fees--paid if claim brought on a "good faith and reasonable basis" regardless of entitlement outcome
- Vaccine Injury Compensation Trust Fund
  - excise tax of 75 cent per "dose" (disease prevented)
  - pays awards/attorneys' fees/costs administrative budgets for the 3 government entities (HHS-HRSA, DOJ and the Court)

Appeals

- 1st level: US Court of Federal Claims
- 2nd level: US Court of Appeals for the Federal Circuit
  - precedent setting
- 3rd level: US Supreme Court

Adding New Vaccines

2-Step Process

- Legislation
  - Congress imposes excise tax for vaccine
- Regulation
  - Secretary adds to VICP newly licensed vaccines *recommended by CDC for routine administration to children*
  - Officially recommended once published in MMWR
- Coverage
  - 8-year retroactive period from the effective date
  - 2-year window to file older claims

"Covered" Vaccines

- Diphtheria, tetanus, pertussis (DTaP, DTP, DTP-Hib, DT, Td, and TT)
- Measles, mumps and rubella (MMR, MR, M, R)
- Polio (IPV and OPV)
- Haemophilus influenzae type b (Hib)
- Hepatitis B (HBV)
- Varicella (VZV)
- Rotavirus (RV)
- Pneumococcal conjugate
- Hepatitis A
- Influenza
- Meningococcal
- Human papillomavirus (HPV)

VICP Significant Events

- Pre-88 filing deadline: January 31, 1991
  - 4,264 pre-88 (DTP 75% of claims)
  - all adjudicated under the "Initial" Vaccine Injury Table
  - $902 million in awards

- Major IOM reviews of vaccine adverse events
  - 1991 (pertussis and rubella vaccines)
  - 1994 (Td/T, MMR, polio, Hib, HBV)
  - 2011 (HAV, HBV, HPV ,influenza, meningococcal, MMR, tetanus-containing (DTaP, Tdap, Td), and varicella
  - 1991 and 1994 reviews Congressionally-mandated

VICP Significant Events (cont.)

- Modifications to the Vaccine Injury Table
  - 1995
    - HHE and seizures removed under DTP
    - chronic arthritis added for rubella-containing vaccines
    - Aids to Interpretation modified for encephalopathy
  - 1997
    - thrombocytopenia added for measles-containing vaccines
    - brachial neuritis added for tetanus-containing vaccines
    - anaphylaxis added for HBV
  - 2002 (RV and intussusception)

- Supreme Court Decision: *Whitecotton v. Shalala* (1995)
  - Unanimous decision for HHS
  - Decision on remand by US Appeals Court for the Federal Circuit set up 4 criteria for determining significant aggravation

VICP Significant Events (cont.)

- Shift from Table to off-Table claims (1996)
  - DTP Table changes
  - switch from DTP to DTaP/OPV to IPV
  - addition of 9 vaccines to VICP, nearly all without injuries
- 2-year filing deadline for HBV claims (1999)
  - bolus of >400 claims
  - put on hold by Court until awaiting theories/experts
- Omnibus Autism Proceeding (2001-2010)
  - >5,600 claims filed—3 theories (MMR, thimerosal, or combination)
  - hearings 2007/2008 led to decisions in favor of HHS 2009/2010
  - some individual cases going forward on other theories
  - Court working with petitioners bar to resolve attorneys' fees/costs in remaining claims

VICP Significant Events (cont.)

- Federal Circuit Decision (2005)
  - Althen v. Secretary, HHS: 3 criteria for determining causation
    - medical theory causally connecting the vaccination and injury
    - a logical sequence of cause and effect showing the vaccination was the reason for the injury
    - showing of proximate temporal relationship between vaccination and injury

- Addition of influenza vaccines (2005)
  - 50% of annual filings
  - doubled number of claims filed annually
  - switch from pediatric to adult program
  - demyelinating disorders (i.e., GBS) most common diagnosis

VICP Statistics
(as of 05-24-12)

- 14,214 claims filed
- Awards
  - Compensation $2.29 billion
  - Attorneys fees/costs $148.6 million
  - Total $2.44 billion

- Trust Fund $3.404 billion

2011 IOM Report

- In new effort to update Table, HRSA/CDC/NPVO funded contract in 2008 for IOM review
  - 8 VICP vaccines (12 of 16 vaccine antigen combinations found in 92% of claims)
  - HAV, HBV, HPV, MMR, influenza, meningococcal, tetanus-containing, and varicella vaccines
- Working list of adverse events generated by HRSA's Division of Vaccine Injury Compensation (DVIC) medical staff based on VICP claims and input from CDC and other HHS agencies in Interagency Group.
- Public input sought through Advisory Commission on Childhood Vaccines (ACCV) and the IOM project website
- IOM Committee added 10 of their own AE's for final working list of 76 or 158 adverse event-vaccine combinations; included 3 adverse events in the general category of injection-related events.
- Final report released 8/25/11
  - No recommendations, only findings

IOM Committee Review Methods

- For each vaccine-AE relationship, IOM made 3 assessments
  1. Weight-of-Epidemiologic Evidence (4 levels = high, moderate, limited, and insufficient).
  2. Weight-of-Mechanistic Evidence (4 levels = strong, intermediate, weak, and lacking).
  3. Causality Assessment: overall assessment made from position of *neutrality* and moved from neutral position only when the combination of epidemiologic and mechanistic evidence suggested a more definitive assessment regarding causation.
- Four categories of causation evidence
  1. Convincingly supports a causal relationship
  2. Favors acceptance of a causal relationship
  3. Inadequate to accept or reject a causal relationship
  4. Favors rejection of a causal relationship

2011 IOM Report

- DVIC and CDC Immunization Safety Office task force developed proposed changes to the Vaccine Injury Table and Qualifications and Aids to Interpretation
  - 11injuries proposed to be added to Table—10/11 from "convincingly supports" category
  - No injuries proposed for removal
  - Revisions, new definitions, clarifications to Aids
- Under the Act, Secretary has authority to modify the Table and Aids via rulemaking, with notice and the opportunity for public comment (180 days), and after consultation with the ACCV
- Proposals approved unanimously by the ACCV at its quarterly meeting on March 8, 2012
- Proposals under review by the Department. Rulemaking with notice and to follow, then final rule

VICP Outcome Measures

- Compensation
  - Awards made to > 2,900 families/ individuals
  - Average time filing to payment is 1.5 years (FY 2008)
- Process improvements
  - no fault, limited discovery, short, informal hearings, use of annuities, trust, and guardianships to ensure stream of benefits
- Marketplace stabilization
  - Supply shortages resolved, high immunization rates, new products being licensed, pricing stability
- Decreased civil litigation
  - Industry lawsuits for VICP-covered vaccines at pre-litigation crisis levels (non-autism claims)
  - similar for healthcare providers

MORE INFORMATION

- VICP Web site: http://www.hrsa.gov/vaccinecompensation/
- VICP Toll-free number: 1-800-338-2382
- US Court of Federal Claims Web site: http://www.uscfc.uscourts.gov/
- IOM Report: http://www.iom.edu/Reports/2011/Adverse-Effects-of-Vaccines-Evidence-and-Causality.aspx

EXTRA SLIDES

IOM Causality Conclusion: Convincingly supports

Vaccine	Adverse Event	VIT Revision
Varicella	Disseminated varicella infection (widespread chickenpox rash shortly after vaccination)	Add (new)
Varicella	Disseminated varicella infection with subsequent infection resulting in pneumonia, meningitis, or hepatitis in individuals with demonstrated immunodeficiencies.	Add (new)
Varicella	Vaccine strain viral reactivation (appearance of chickenpox rash months to years after vaccination)	Add (new)
Varicella	Vaccine strain viral reactivation with subsequent infection resulting in meningitis or encephalitis (inflammations of the brain)	Add (new)
MMR	Measles inclusion body encephalitis	Add (under vaccine strain measles dz)
MMR	Febrile seizures (a type of seizure that occurs in association with fever and is generally regarded as benign)	No change (no long-term sequelae)

IOM Causality Conclusion: Convincingly supports

Vaccine	Adverse Event	VIT Revision
MMR	Anaphylaxis	No change (already there)
Varicella	Anaphylaxis	Add (new)
Influenza	Anaphylaxis	Add (new)
Hepatitis B	Anaphylaxis	No change (already there)
Tetanus Toxoid	Anaphylaxis	No change (already there)
Meningococcal	Anaphylaxis	Add (new)
Injection-Related Event	Deltoid bursitis (frozen shoulder, characterized by shoulder pain and loss of motion)	Add (to all injected)
Injection-Related Event	Syncope (fainting)	Add (to all injected)

IOM CAUSALITY CONCLUSION: FAVORS ACCEPTANCE

Vaccine	Adverse Event	VIT Revision
HPV	Anaphylaxis	Add-new
MMR	Transient arthralgia (temporary joint pain) in women	No change – no long term sequelae[a]
MMR	Transient arthralgia in children	No change – no long term sequelae
Influenza	Oculorespiratory syndrome (a mild and temporary syndrome characterized by conjuctivitis, facial swelling, and upper respiratory symptoms)	No change – particular vaccine not manufactured[b]

[a] The committee attributes causation to the rubella component of the vaccine

[b] The committee attributes causation to 2 vaccines used in three flu seasons in Canada

IOM Causality Conclusion: Favors Rejection

Vaccine	Adverse Event	VIT Revision
MMR	Autism	No change – not currently listed
Influenza	Inactivated influenza vaccine and Bell's palsy (weakness or paralysis of the facial nerve)	No change – not currently listed
Influenza	Inactivated influenza vaccine and asthma exacerbation or reactive airway disease episodes in children and adults	No change – not currently listed
MMR	Type 1 diabetes	No change – not currently listed
DT, TT, or aP containing	Type 1 diabetes	No change – not currently listed

IOM Causality Conclusion: Inadequate to accept or reject

Vaccine	Adverse Event	VIT Revision
Influenza	Asthma exacerbation	No – no long term sequelae
Influenza	Febrile seizures	No – no long term sequelae
Influenza	Guillain–Barré syndrome (GBS)	No change – not currently listed
Hepatitis A	Anaphylaxis	No – evidence not available
DT, TT, or aP containing	Encephalopathy/encephalitis	Yes – already listed on Table but QAI will be updated
Injection-Related	Complex Regional Pain Syndrome	No – not enough evidence yet