

Overview of Liability and Compensation Issues with Immunization of Pregnant Women

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Outline

- I. History of vaccine liability
- II. VICP overview
- III. Maternal Immunization and VICP Case Law
- IV. HHS interest in maternal immunization

History of Vaccine Liability

- Originally, handled in civil court system.
- All parties dissatisfied.
- Push for tort reform nationally.
- Congress responded with National Vaccine Injury Compensation Program (VICP).

VICP

- Federal, no-fault alternative to civil system.
- Provides compensation to “eligible petitioners” for vaccine related injuries and deaths caused by “covered vaccines.”

Covered Vaccines

- Vaccines recommended by the CDC for routine administration to children.
- Added to the Vaccine Injury Table by the Secretary of Health and Human Services.
- Effective on passage of excise tax.

List of Covered Vaccines

- Vaccines containing tetanus toxoid (e.g., DTaP, DTP, DT, Td, TT)
- Vaccines containing whole cell pertussis bacteria, extracted or partial cell pertussis bacteria, or specific pertussis antigen(s) (e.g., DTP, DTaP, P, DTP-Hib)
- Measles, mumps and rubella vaccine or any of its components (e.g., MMR, MR, M, R)
- Vaccines containing rubella virus (e.g., MMR, MR, R)
- Vaccines containing measles virus (e.g., MMR, MR, M)
- Vaccines containing polio live virus (OPV)
- Vaccines containing polio inactivated (e.g., IPV)
- Hepatitis B vaccines
- Hemophilus influenzae (type b polysaccharide conjugate vaccines)
- Varicella vaccine
- Rotavirus vaccine
- Pneumococcal conjugate vaccines
- Hepatitis A vaccines
- Trivalent influenza vaccines
- Meningococcal vaccines
- Human papillomavirus (HPV) vaccines
- Any new vaccine recommended by the Centers for Disease Control and Prevention for routine administration to children, after publication by Secretary, HHS of a notice of coverage

Process

- Eligible individual must first file claim in the VICP against Secretary of Health and Human Services.
- Must prove:
 - Eligibility to file.
 - Sustained injury listed on Vaccine Injury Table (causation presumed) or off-Table (must prove causation).
- No fault.
- Manufacturer/administrator are not parties.

Forum

- U.S. Court of Federal Claims.
- Decided by Special Master (trial judge).
 - Not binding.
- Appealable to U.S. Court of Appeals for the Federal Circuit and U.S. Supreme Court.
 - Binding.

Post-VICP

- Petitioner must accept or reject judgment.
- If accept, then matter is final.
- If reject, then can sue manufacturer or administrator in civil court (limitations).

Not Eligible?

- Not required to file in the VICP. May bring civil suit directly.
- If file in VICP and found ineligible, case is dismissed.

Maternal Immunization in the VICP

- Claims for mother's own injuries.
- Claims for injuries to fetus.

Relevant Statutory Language

- Petitioner must prove “that **the person who suffered such injury or who died...received a vaccine** set forth in the Vaccine Injury Table or if such person did not receive such a vaccine, contracted polio, directly or indirectly, from another person who received an oral polio vaccine” 42 U.S.C. 300aa-11(c)(1)
- “Only one petition may be filed with respect to each administration of a vaccine.” 42 U.S.C. 300aa-11(b)(2)

VICP Cases

- VICP parties have not agreed on the meaning of these provisions.
- Special Masters have not come to a consensus.
 - Some say can bring *in utero* claim.
 - Interpret “received” broadly to match remedial nature of the statute.
 - Some say cannot bring *in utero* claim.
 - Interpret “received” narrowly. Expression of one indirect method (oral polio exception) is the exclusion of all other indirect methods (*in utero* receipt).
- One petition rule not widely addressed by special masters.
- No cases have reached the Federal Circuit. No binding precedent. Not settled one way or the other.

Issues with Coverage of Vaccines

- Vaccines under development (RSV, GBS), if approved, may only be exclusively recommended for pregnant women.
- Statute limits covered vaccines to vaccines that are “recommended for routine administration in children.”
- Potential to cover these vaccines?

HHS Interest in Maternal Immunization

- Influenza, Tdap
- Healthy people 2020 Goals
- Countermeasures Injury Compensation Program (CICP)
- NVAC, ACCV

CICP

- Provides compensation for injuries and deaths directly caused by the administration or use of “covered countermeasures” used in public health emergencies.
- HRSA exercised its broad authority under the Public Readiness and Preparedness Act to promulgate regulations to implement the CICP.
- Issued regulation that specifies a child can qualify as an injured countermeasure recipient if the child survives birth, and is born with, or later sustains, a covered injury as the direct result of the mother’s administration or use of a covered countermeasure during pregnancy. *See* 42 C.F.R. 110.3(n), and preamble discussion at 75 FR 63660.

Thank You.