

Overview of Liability and Compensation Issues with Immunization of Pregnant Women

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Outline

- I. Relevant statutory provisions
- II. Maternal Immunization and VICP
Case Law
- III. HHS interest in maternal immunization

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).

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 (and miscarriage).

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 and judges 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.”
- How can these vaccines attain coverage?

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.
- Note differences between CICP and VICP. CICP statute gives broad authority to promulgate regulations to administer the program. VICP statute has specific authority to revise the Table and determine cost of health insurance. VICP only covers vaccines. CICP covers countermeasures other than vaccines, such as antiviral that can be inhaled or ingested. The CICP regulation on countermeasure recipient is in reference to a variety of countermeasure products. VICP statute is in reference to vaccines.

Thank You.