Overview of Liability in the U.S. for Maternal Immunization

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Outline

I. History of vaccine liability
II. VICP overview
III. Maternal Immunization and VICP Case Law
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 for vaccine related injuries and deaths caused by “covered vaccines.”
Covered Vaccines

- Vaccines recommended by CDC (ACIP) for routine administration to children.
- Added to the Vaccine Injury Table by the Secretary of Health and Human Services.
- Effective on excise tax.
List of 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 (trivalent)
- Meningococcal
- Human papillomavirus
Process

• First must file claim in the VICP against Secretary of Health and Human Services.

• Must prove:
  – Received a covered vaccine.
  – 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/administrator in civil court (limitations).
Maternal Immunization in the VICP

- Claims for mother’s own injuries.
- Claims for injuries to fetus (and miscarriage).
• 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)
Di Roma v. HHS
1993 WL 496981 (1993)

• *In utero* injury claims are **Not** compensable in the VICP.
• Clear requirement that the injured person must have **received** a covered vaccine.
• Special Master decision. Not binding.
Rooks v. HHS
35 Fed. Cl. 1 (1996)

- *In utero* injury claims are compensable.
- Remedial statutes ought to be interpreted broadly.
- Court of Federal Claims decision. Not binding.
- On remand, Special Master held petitioner failed to prove that the mother’s measles vaccination actually caused her son’s congenital defects.
In utero injury claims are not compensable.

– Strict interpretation because doctrine of sovereign immunity.

– Only the individual directly injected with the vaccine can be said to have “received” it.
Burch v. HHS
2010 WL 1676767 (2010)

- *In utero* injury claims are compensable.
  - Supreme Court case law on “sovereign immunity doctrine” had changed.
  - Special Master felt no longer compelled to give narrow definition of “received.” Adopted broad definition.

- Both are special master decisions. Not binding.
Melton v. HHS

– *In utero* claims are not compensable.
– Statute only expresses one indirect method of “receipt” (oral polio).
– *Expressio unius est exclusio alterius* ("expression of one is the exclusion of all others").
– Special master decision. Not binding.
Death Claims

  - No compensation for mother’s own injury of miscarriage (could not prove causation).
  - No compensation for child’s death—withdrawn claim before resolved.

- Only the “legal representative” may file a death claim.
- Determined under state law.
- New York state law said cannot be a legal representative of someone not born alive.
Injuries to Pregnant Women

• Interpretation of “receipt” not at issue because of direct receipt.

• Compensable.
Conclusion

• Short of a decision by the Federal Circuit or an amendment to the Vaccine Act, compensability under the VICP for *in utero* injuries is unsettled.

• Compensability under VICP for injuries to pregnant women is settled.