Inclusion of Pregnant and Lactating People in Clinical Trials: Surveying the Legal Landscape

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Mapping the Landscape: Overview

Caution: Complexities of the Legal Terrain

Legal Factors that Slow or Halt Inclusion

Pathways Forward

Anticipating Legal Changes Ahead

Complexities of the Legal Terrain

Different Legal Regimes

Pregnancy / Lactation

- **Human subjects research regulations**
- **-** 45 C.F.R. 46, Subpart B
- **Liability for harm**
- **-** Prenatal v. postnatal

*Drugs / Vaccines

Drug development and approval regulations

- NDA v. BLA

Liability schemes

- Private v. public

Non-Public Health Emergency (PHE) / PHE

FDA development and approval process

- Emergency Use Authorizations

Liability Schemes

- Immunity from liability for activities related to medical countermeasures

* Generally small molecule

Legal Factors that Can Slow or Halt Inclusion

Legal considerations can influence decisionmaking at every stage of product development.

-- Mastroianni AC, Henry LM, et al. (2017).

- Regulatory ambiguity
- Perceptions of liability
- Risk management challenges
- Risk shifting and the ”learned intermediary doctrine”
- Venue specific laws

Mastroianni AC, Henry LM, et al. Research with Pregnant Women: New Insights on Legal Decision-Making. *Hastings Center Report*. 2017;47(3):38-45.

Pathways Forward and Anticipating Changes Ahead

Pathways Forward

- Regulatory revisions
- Regulatory guidance
- Research and education related to liability
- Investigate feasibility of various injury compensation schemes
- Legal / financial incentives

Changes Ahead

- Dobbs v. Jackson Women's Health Organization
- State law changes