# Accelerated Approval

## Background

# History

- 1906 – FDA created, weak authority over drugs
  - Few effective drugs available
- 1938 – Food, Drug and Cosmetic Act enacted
  - Required proof of safety for new drugs
- 1962 – Effectiveness standard for drugs added to safety provision
- 1970s - 1990s – “Drug Lag” with other countries
- 1970s – Group C cancer drugs
- 1970s – Present – Emergence of “Conditional” Approval Concepts
  - Initial FDA safety screen
  - Efficacy established by clinical use

# Accelerated Approval Regulation

- 1987 – AZT approved
  - Based on a laboratory measurement ( increase in CD4 immune cells, i.e., a surrogate endpoint)

- April 1992 – Accelerated Approval Regulation Proposed
  - Serious and Life-Threatening conditions
  - NOT conditional approval, Medicare should reimburse

- December 1992 – Accelerated Approval Regulation Finalized
  - “Approval can be reliably based on evidence of the drug’s effect on a surrogate endpoint that reasonably suggests clinical benefit”
  - Confirmation via postmarketing studies

# Since Policy's Adoption

- Congress codified regulation into statute (2012)
- Ca. 300 drugs/indications approved
- Significant patient benefit
- BUT, criticisms:
    - Delays in confirmatory trials
    - Slow withdrawal from market for failed confirmations
    - Weakening of the Efficacy Standard
    - Aduhelm approval/CMS coverage decision