

# Policies: What's Possible? Private Sector

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# Change at What Level?

- Consider changes above the level of clinical trials:
  - Equity in access to clinical trials is a desirable and appropriate outcome; yet the current approach to developing new drugs, including the approach to clinical trials is flawed; and there are better options, though slow to arrive.
  - Likewise universal access to care would remove some of the disparities that equitable trials raise

# The Future will Be Different (1)

- Significant trends that might affect clinical trials:
  - Side effect and other major Rx problems, e.g. Vioxx; Direct to consumer advertising, electronic medical records; pharmacogenomics; FDA's Critical Path Initiative; smarter self/home biomonitoring, smarter self care;
  - Globalization, Rx research, testing, and manufacture in India, Eastern Europe, China, and other developing countries – US trained MDs conducting trials in all of these places
  - Possibly using prisoners in clinical trials

# The Future will be Different (2)

- Alternative Environments/Business Models
- Bottom of the Pyramid Focus
- Congress changes the drug regulation process
- Shift role of FDA from gate keeper to odds maker
- Virtual patients, virtual cohorts, virtual trials
- Increasing health care quality, electronic medical records, monitoring of efficacy & side effects
- Incorporating pharmacogenomics, phenotypic knowledge into medical practice and drug development
- Universal access to effective health care?

# Pharma company view

- Typically seeking high return; have increasing costs:
  - Pharma R&D spending: \$100 billion 1992 - \$250 billion 2002
  - Typical Cost NME → Market: 1995-2000 \$1.1 billion -- 2000-2002 \$1.7 billion
    - Increased clinical trial costs due to high tech laboratory, radiology and pathology components, higher charges by clinics performing the clinical trials, regulatory agency insistence on more trials, long follow up of patient, large numbers of patients.
    - High failure rate because of difficulty in predicting efficacy from the research phase
- It is good to include poor, minority patients if they have health coverage and the patients will be compliant and trackable; ultimately will consider relative costs of the clinical trials
- Most pharma companies don't see the changes until they are upon them