

# Challenges to Industry's Adoption of Alternatives

(from my experience)

- Desire for “regulatory” acceptance whether or not a regulated product.
  - Liability concerns
- Concern about disapproval of animal welfare, or other special interest groups
  - BCOP uses animal parts
  - Source of human cells

**Solution: Honest dialogue between groups!**



# Challenges to Industry's Adoption of Alternatives - II

- Availability of appropriate tests
  - Not all toxic endpoints are adequately covered by alternative tests

**Solution: More funding made available for mechanism-specific development.**

- Costs
  - In vitro tests are not necessarily cheaper!
  - Generally more rigorous protocols
  - **Solution?: More automation; understanding of value added?**



# Challenges to Industry's Adoption of Alternatives - III

- Has it been made a company priority?
- Availability of testing facilities ??



# Barriers to Regulatory Acceptance I

- Comfort level by gatekeepers or regulatory users not high

**Solution: Instruction and hands-on experience with tests**

- No incentive for regulators to change

**Solution: Make the move to scientifically valuable alternatives an Agency priority**

- Fear of animal welfare groups gaining an advantage

**Solution: Education and dialogue**



# Barriers to Regulatory Acceptance II

- Lack of understanding of the predictive capacity of the animal model.
  - Partially due to lack of data; often due to lack of desire

**Solution: Further development of current ICCVAM statistical projects**

