

# Adolescent over-the-counter drug use

**Welcome to Day 2**

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# Insights from Day 1

- Opportunity to hear from varied perspectives
  - Regulatory
  - Scientific
  - Industry
  - Clinical

# Insights from Day 1

- Research tools exist for studying OTC-relevant behaviors pre-approval
- These tools can be applied to adolescents (Dr. Nikhar) – interpretation of that data?
  - Intent to heed not uniformly high
  - Some key messages not well understood, particularly by lower-literacy adolescents
  - Determinants of behavior not clear – price in the case of orlistat
  - Age per se not effective direction on adult labels

# Kids are not little adults

- Adolescents differ from adults
  - Biology
  - Physiology
  - Behaviors/decision making
  - Neuro-development

# Insights from Day 1

## ■ Adolescents differ

- Structural/functional correlates provide scientific foundation to concept of maturation of decision making
- Relevant to “judgment” and “risk taking”
- Not clear that age a reliable surrogate for maturation of decision making

## ■ Environmental factors interact with host factors

- Peer presence
- Need for new warning?

DO NOT USE:

If allergic...

If any of your friends are in the room...

# Insights from Day 1

- Focusing on use of OTC with therapeutic intent:
  - Not clear IF there is a problem (absence of evidence, not evidence of absence)
  - IF there is a problem, is it one of judgment or one of knowledge/misconception
  - Data on adolescent OTC use characterized by breadth but not depth
  - Likely masks heterogeneity on how drugs used (consistent with heterogeneity of population)
  - How to judge the importance of mis-use:

*Magnitude of problem  $\approx$  Frequency of non-heeding  $\times$   
Risk associated with the specific non-heeding*

# Insights from Day 1

- Mandate from public (Congress) to understand factors specific to pediatric/adolescent use of drugs
- Need to understand the public health issues to apply the new learnings about the population
- Differentiate drug abuse from errors with therapeutic intent
- Issue-specific interventions
  - Broad public communications – example of drug abuse campaign for effective elements
  - Need for drug-specific labeling to address adolescent behaviors identified

# Sets the stage for Day 2....

- How do we communicate with adolescents on issues of OTC drug use?
- Roundtable – moving forward