

# FDA's Cigarette Graphic Health Warnings



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## Disclaimers

The information in this presentation is not a formal dissemination of information by FDA and does not represent agency position or policy.

I will not discuss pending litigation or FDA's plans for legal or policy actions on graphic health warnings.

# Family Smoking Prevention and Tobacco Control Act Selected Authorities

- Requires nine new larger and more noticeable textual warning statements to appear on cigarette packages and in cigarette advertisements.
- Directs FDA to issue regulations requiring that color graphic images depicting the negative health consequences of smoking accompany the nine new textual warning statements.

# Why Graphic Health Warnings?

- Pictorial warnings lead to greater levels of awareness and understanding of health risks
- Evidence suggests that Graphic Health Warnings may shift behavior, including:
  - reducing cigarette demand and consumption
  - increasing abstinence
  - increasing motivation to quit
  - promoting calls to quitlines
  - promoting cessation
  - preventing youth initiation

# FDA Graphic Health Warnings Study

- On-line study conducted by FDA in 2010
- 36 experiments ( $N = 13,500$ )
  - Each warning statement was paired with multiple images vs. control condition
  - Three sample groups
    - Current adult smokers (25 years and older)
      - Exposure on a cigarette pack or as part of an advertisement
    - Young adult smokers (18-24 years old)
      - Exposure on a cigarette pack
    - Youth smokers or youth susceptible to initiation
      - Exposure on a cigarette pack

# FDA Graphic Health Warnings Study

Example:  
Control Condition



Example:  
Treatment Condition



# FDA Graphic Health Warnings Study

- Assessed after exposure
  - emotional and cognitive reactions
  - recall of images and statements
  - influences on beliefs about health risks of smoking and secondhand smoke
  - quit intentions among smokers and self-reported likelihood of smoking 1 year from now among youth
- Assessed at 1-week follow-up
  - recall of images and statements

# FDA Selection of Proposed Graphic Health Warnings

- Selection based on:
  - Relative efficacy (as compared to control) of the GHWs in FDA's experiments, primarily for increasing salience of warnings to participants.
  - Other factors, including public comments, scientific literature, variety and diversity in visual style employed in GHW.







# Research Questions for Graphic Health Warnings

- What is the influence of cigarette graphic health warnings on cognitive and affective factors among vulnerable populations?
- What is the relative effectiveness of specific health warnings among youth and other vulnerable populations?
- In order to achieve maximum effectiveness, how often should health warnings be replaced with different warnings?

**DISCLAIMER: The research questions on this slide represent my own ideas/opinions, and not necessarily that of the FDA.**

# Research Questions for Graphic Health Warnings

- What are the best methods to measure the effectiveness of warnings?
  - Behavioral outcomes
    - Immediate and long-term
    - Initiation and cessation/quit attempts
  - Measures of exposure
- How can we improve text-based warnings alone or when accompanying images?

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