FDA’s Cigarette Graphic Health Warnings

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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.
WARNING: Cigarettes are addictive.
1-800-QUIT-NOW
© U.S. HHS

WARNING: Tobacco smoke can harm your children.
1-800-QUIT-NOW
© U.S. HHS

WARNING: Cigarettes cause fatal lung disease.
1-800-QUIT-NOW
© U.S. HHS

WARNING: Smoking during pregnancy can harm your baby.
1-800-QUIT-NOW
© U.S. HHS

WARNING: Cigarettes cause cancer.
1-800-QUIT-NOW
© U.S. HHS

WARNING: Tobacco smoke causes fatal lung disease in nonsmokers.
1-800-QUIT-NOW
© U.S. HHS

WARNING: Smoking can kill you.
1-800-QUIT-NOW
© U.S. HHS

WARNING: Quitting smoking now greatly reduces serious risks to your health.
I QUIT
© U.S. HHS
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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