Tobacco-related risk perceptions in the regulation of tobacco products at the FDA Center for Tobacco Products

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Disclaimer

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

Specific Authorities of FDA under the Family Smoking Prevention and Tobacco Control Act

- Restrict youth access to tobacco products
- Enforce advertising and promotion restrictions
- Premarket applications for modified risk tobacco products and new tobacco products
- Harmful and potentially harmful constituent testing and reporting by brand and sub-brand
- Establishing tobacco product standards
- Health warnings on marketed packages & ads
- Registration and ingredient listing
- Ingredient reporting
- Authority to conduct research to support tobacco product regulation

PATH

Population Assessment
of Tobacco and Health

What is the PATH Study?

- The PATH Study is a **large (*N* ~ 59,000), national, representative longitudinal cohort study of tobacco use and health in the United States** which will measure tobacco use behaviors and related health effects.

- The Study's baseline data collection is scheduled for the fall of 2013 with a cohort of **never, current, and former users of tobacco products ages 12 years and older**.
  - The cohort will then be followed annually for at least three additional data collection waves.

Longitudinal Study Design

- Tobacco use and changes over time
- Tobacco use initiation, cessation, and relapse
- Poly tobacco use and switching between products
- Emergence of addiction and dependence
- Tobacco related disease
- Changes in awareness, knowledge, attitudes, perceptions
- Attitudes towards and use of novel tobacco products
- Assessing impact of changes in tobacco products over time

Specific Aims of PATH

- Identify trends in tobacco use patterns, including **use of new products, dual use, poly use and switching;**
- Characterize tobacco use **initiation, dependence, cessation, and relapse patterns**;
- Monitor change in **risk perceptions and other attitudes** such as social acceptability and individual preferences;
- Compare intermediate endpoints and ultimately, short- and long-term incidence/prevalence of **health outcomes and cause-specific mortality** among users of different products;
- Assess differences between and within **critical subgroups** including youth, young adults, daily users, racial/ethnic minority groups, and users of new tobacco products; and
- Collect biospecimens to analyze **exposure to harmful constituents.**

HARMFUL AND POTENTIALLY HARMFUL CONSTITUENTS (HPHC)

HPHC overview

- In guidance published in January 2011, FDA defines HPHC as:

  any chemical or chemical compound in a tobacco product or in tobacco smoke:
  a) that is or potentially is inhaled, ingested, or absorbed into the body; and
  b) that causes or has the potential to cause direct or indirect harm to users or non-users of tobacco products.

- In March 2012, FDA established a list of 93 HPHC and published a draft guidance to industry regarding the reporting of HPHC to FDA.

Reporting on HPHC

- Industry required to report HPHC to FDA

- FDA must publish in a format that is understandable and not misleading to a lay person…a list of harmful and potentially harmful constituents, including smoke constituents, to health in each tobacco product by brand and by quantity in each brand and subbrand.

- FDA must conduct periodic consumer research to ensure that the list is not misleading to lay persons.

FDA Focus Group Research on Perceptions of HPHC

- 16 focus groups (n=149)
  - Greenbelt MD, Miami FL, Nashville TN, Baton Rouge LA
- Segmented by gender, age, education, and smoking status
- Assessed knowledge and perceptions about HPHC in tobacco products
    - The risks of using tobacco
    - Knowledge of harmful chemicals that may be in tobacco products
    - The source of harmful chemicals in tobacco products
- Assessed possible reactions to lists of HPHCs

FDA Focus Groups on Perceptions of HPHC – Overview of Findings

- Limited knowledge about chemicals in tobacco and tobacco smoke.
- Very few knew where the chemicals come from.
- Majority believed all the chemicals are added by the tobacco company.
- Most unaware that chemicals are produced when tobacco is burned.

FDA Quantitative Research on HPHC Lists (planned)

- Purpose: to assess comprehension and risk perceptions of products following exposure a HPHC list using mock brands

- Sample: internet panel (n=3,150)
  - Adult smokers age 25 and older
  - Young adult smokers age 18-24
  - Youth tobacco users age 13-17
  - Youth susceptible to smoking age 13-17

FDA Quantitative Research on HPHC Lists - Method (planned)

- Design: 3 (list format) X 3 (product type: cigarettes, roll-your-own, smokeless) X 2 (additional information: present, absent) partial factorial

- Outcomes:
  - Comprehension of list content
  - Risk perceptions of products

MODIFIED RISK TOBACCO PRODUCT (MRTP) APPLICATIONS

Modified Risk Tobacco Products

- In general, an MRTP is a tobacco product sold or distributed for use to reduce harm or the risk of tobacco-related disease; including products whose label, labeling or advertising :
  - Represents that the product is less harmful or presents a lower risk of tobacco-related disease than other commercially marketed tobacco products;
  - Represents that the product or its smoke contains a reduced level of, presents a reduced exposure to, or does not contain/is free of a substance;
  - Uses the terms “light”, “low” or “mild”;
  - One for which someone has made statements through the media, or otherwise, representing that the product poses less risk or harm

Modified Risk Tobacco Products

- In order for an MRTP to be legally introduced or delivered for introduction into interstate commerce
  - An application must be filed with FDA, and
  - FDA must issue an order allowing it to be commercially marketed or introduced or delivered for introduction into interstate commerce.

FDA Recommended Research for MRTP Applications

- In March 2012 FDA issued a draft guidance for industry on submitting MRTP applications that included research recommendations :
  - Health Risks of the Tobacco Product
  - Effect on Tobacco Use Behavior among Current Tobacco Users
  - Effect on Tobacco Use Initiation among Non-Users
  - Effect of Marketing on Consumer Understanding and Perceptions
  - Effect on the Population as a Whole

Effect of Marketing on Consumer Understanding and Perceptions

- Ability of consumers to understand the modified risk information and the significance of the information in the context of one's total health;
- Beliefs about the health risks of using the product as compared to other products;
- Beliefs about the health risks of using the product relative to cessation aids; and
- Beliefs about the risks of using the product relative to quitting all tobacco use.

Questions?

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http://www.fda.gov/TobaccoProducts