- Possible effects of modified risk tobacco products on smoking cessation, relapse, and initiation

- Risk perception, risk communication

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Key messages

Usage patterns, risk perception/communication:

- Both lines of inquiry represent growing areas of tobacco research.
- Standards do currently exist and useful studies have been conducted, particularly relating to cessation, relapse, and initiation, and related "behavioral factors".
- In the short term, valid tobacco harm reduction (THR) modeling based on postmarket surveillance data can effectively support decision making - although data gaps exist.
Cessation, Relapse, Initiation

- Significant number of US studies based on established surveys have been published since passage of the Tobacco Control Act
- Historically much research on population uptake of snus has been conducted in Sweden and other Scandinavian countries
- There is extensive epidemiological data on consumers of Swedish snus
Epidemiological research in Sweden

- Comprehensive registers of the total population and emigration/immigration
- Large number of cohorts formed over the years that permit tobacco-related research
  - Construction Worker Cohort, Malmö Diet & Cancer Cohort, MONICA cohorts, Västerbotten cohorts, etc
- National registers on health outcomes
  - Swedish Cancer Registry, Cause-of-Death Registry, Registry of Hospital Admissions, National Registry of Myocardial Infarctions, Swedish Twin Registry
- Applicability of Scandinavian data to the US Tobacco Control Act
  - Product specific (snus)
  - Studies on health outcomes among individual users have substantial external validity
  - Studies on population usage patterns potentially relevant
US Research

- At least 13 national, large-scale quantitative survey programs that address tobacco usage
  - Including the National Health and Nutrition Examination Survey (NHANES), the National Health Interview Survey (NHIS), the National Survey on Drug Use and Health (NSDUH), and the Tobacco Use Supplement to the Current Population Survey (TUS)
  - Most existing surveys governmentally sponsored
  - Sample sizes range from 10,000 12+ y.o. (NHANES) to 240,000 15+ y.o. (TUS)
  - Data acquisition methodologies vary (mainly in-home interviews and telephone interviews)
  - Study frequency varies, majority of studies every 2 years

- While many programs have potential, it is unlikely that any of them, in their present form, will be adequate for rigorous post-market surveillance
  - Lack of sufficient detail on products.
  - Study frequency
  - Several deal solely with adolescents
  - Cross sectional design

- Industry-funded post-market surveillance data will be needed, at least in the short term
  - Either individual companies, or a category consortium created specifically for post-market evaluations
The smokeless industry is aware of the need for accepted scientific standards and has funded reviews conducted by Collilla (2010) and Lee (2011).

Collilla cited studies that have been conducted and concluded more standardized research is needed in the long term. In particular, more sophisticated models will prove necessary to determine relationship between ST use and cigarettes.

Collilla cited the promise – and challenge – of establishing a standard model to represent the gateway hypothesis.


- Identified needed research to develop methods and measures related to modified risk decision-making under the Tobacco Control Act.
- Cited the need to evaluate multiple factors through a modeling approach to determine a product’s effect on public health.
- Identified factors associated with determining population harm.

Scientific Committee on Emerging and Newly Identified Health Risks (SCENIHR)

Recent SCENIHR reports to the EU Directorate-General for Health & Consumers (DG SANCO)

Path forward

- Existing frameworks for data collection are inadequate to assess emerging population risks & benefits associated with tobacco harm reduction products or policies.

- Epidemiological studies ideal, but not expedient, for evaluating effectiveness of THR:
  - Will require detailed and repeated exposure assessments (cohorts, repeated panels) to avoid confounding.
  - Identification of relevant health outcomes.
  - Planning, execution will take several years.

- Tobacco Harm Reduction (THR) models, although invariably simplistic, can support decisions and policy development in the short run.
Proposed THR models

Dynamic models:

- Tobacco Policy model (TPM)
- SimSmoke
- Multistate life tables
- PREVENT
- Chronic Disease Model (CDM)
- Apelberg et al
- Mejia et al
- Bachand et al

Static models:

- POPMOD
- DISMOD
- SAMMEC
- DEMANDS
- Gartner et al
Opportunities offered by valid THR models

- Clear specification of underlying assumptions promotes critical evaluations of results
- Modeled results can be validated against other modeling approaches and observational data.
- Models can be revised as new data become available.
- Pragmatic approach to evaluating products that might reduce harm to consumers.

- Promotes rational processes for making decisions and policies.
The short-term challenge is to counter the perception that all tobacco products pose similar risks
- Correct risk perception drives consumer behavior (Biener & Bogen, 2009)

Evidence based risk communication from manufacturers is difficult to accomplish given their restrictions to characterize products

No unified message from academia and NGOs

State of the Science: O’Connor (2011)

The 2006 IOM Committee report *The Future of Drug Safety: Promoting and Protecting the Health of the Public*

- Highlighted risk communication generally and referenced FDA’s mission of helping the public get the accurate, science-based information they need...

Establishment of an FDA-wide *Risk Communication Advisory Committee*

2009 FDA *Strategic Plan for Risk Communication* presented *Actions to Strengthen Science Strategy* including:

- Develop an expert model to characterize the tobacco-use related consumer decision-making and better understand the likely impact of FDA oversight of tobacco products

- FDA-CTP not mandated to conduct a risk communication program
- Thank You -