The information in these materials is not a formal dissemination of information by FDA and does not represent agency position or policy.
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No relationships to disclose
THE SCIENCE OF TOBACCO REGULATION

- **Product**
  - Chemistry
  - Engineering
  - Microbiology

- **Tobacco Product User**
  - Toxicology
  - Pharmacology
  - Clinical medicine
  - Addiction
  - Product use behavior

- **Population as a Whole**
  - Environmental assessment
  - Epidemiology
  - Consumer perception
  - Statistical analysis
  - Evaluation
SCIENTIFIC EVIDENCE HAS A DIRECT IMPACT ON FDA REGULATORY ACTIONS

- Restrict product changes to protect public health
- Prohibit modified risk claims that state/imply reduced exposure or risk without an order
- Decrease the harms of tobacco products
Tobacco Products are changed by the manufacturer to:

- Increase product share
- Attract new users
- Adjust to supply issues
- Retain current users as their preferences change
MANUFACTURERS HAVE CHANGED PRODUCT CHARACTERISTICS

- January 1999
- 2000
- “Before 2002”
- August 2004
- December 2006
- May 2007

Unprotonated (free) Nicotine (mg/g)
• No regulated tobacco product can be changed or first introduced to market after March 21, 2011 without FDA evaluating the science and issuing a marketing order.
• Products changed or introduced between February 15, 2007 and March 20, 2011, may be marketed in a provisional status awaiting FDA review of their SE reports submitted before March 23, 2011.

• **New tobacco product applications:**
  - The primary statutory pathway to market
  - Premarket review
  - Permitting the product to be marketed would be appropriate for the protection of public health.
Substantial equivalence (SE)

• An alternative to new product applications; characteristics are the same as grandfathered products or characteristics are different but the product does not raise different questions of public health.

• Substantive scientific review has begun on all regular SE Reports

• FDA has fully resolved 45% of regular SE reports received to date either through an SE/NSE decision or by the report being withdrawn (most after receiving a deficiency letter).

• FDA is also actively reviewing provisional SE reports (prioritized according to their potential to raise different questions of public health)
Substantial equivalence exemption

• An alternative to substantial equivalence in which the only change is to an additive, the product change is minor and a full substantial equivalence report is not necessary to ensure that permitting the tobacco products to be marketed is appropriate for the protection of public health.
DESIGN CHARACTERISTICS CAN ALTER CONSTITUENT DELIVERY OR PRODUCT USE

**Paper**
- Porosity
- Diffusivity
- Low ignition propensity
- Salt content
- Burn rate

**Tipping paper**
- Pressure drop
- Tip ventilation

**Tobacco filler**
- Blend
- Additives/acidity
- Cut Size
- Moisture

**Cellulose acetate filter**
- Denier (fiber density)
- Efficiency
- Resistance to draw
- Additives
Modified risk tobacco product” means any tobacco product that is *sold or distributed* for use to reduce harm or the risk of tobacco-related disease associated with commercially marketed tobacco products.

The term “sold or distributed” includes labeling and advertising, as well as any communication actions “directed to consumers through the media or otherwise.”
THE STATUTE REQUIRES EVALUATION OF BOTH MODIFIED RISK AND MODIFIED EXPOSURE CLAIMS
EVALUATION OF MODIFIED RISK CLAIMS MUST ADDRESS IMPACT ON THE POPULATION AS A WHOLE

Increased Harm

- Product is more toxic to the user
- Instead of quitting, smokers become dual users
- Products are used in a way that makes them more harmful
- Youth/Adults initiate more
- Former smokers relapse more

Reduced Harm

- Product is less toxic to the user
- Smokers switch completely to less toxic products
- Products are used in a way that makes them less harmful
- Initiation is reduced
- Former smokers relapse less
“Use of tobacco products is driven by their appeal or attractiveness to potential consumers and sustained by their pharmacological addiction or dependence potential.”

Non-use

↓

Experimentation

↓

Addiction

↓

Disease and Death

STATUTORY BASIS FOR TOBACCO PRODUCT STANDARDS

Through rulemaking, the Tobacco Control Act allows adoption of “...tobacco product standards... appropriate for the protection of public health.” Sec 907.

- Nicotine yields
- Reduction or elimination of constituents, including smoke constituents
- Construction, components, ingredients, additives, constituents, and properties of the tobacco product
- Provisions for testing or measuring product characteristics
- Restrictions on sale and distribution
- Form and content of labeling
## SMOKING CESSATION LEADS TO BETTER HEALTH OUTCOMES

<table>
<thead>
<tr>
<th>Age at time of quitting smoking</th>
<th>Additional life expectancy due to quitting</th>
</tr>
</thead>
<tbody>
<tr>
<td>30 years old</td>
<td>Almost 10 years</td>
</tr>
<tr>
<td>40 years old</td>
<td>9 years</td>
</tr>
<tr>
<td>50 years old</td>
<td>6 years</td>
</tr>
<tr>
<td>60 years old</td>
<td>3 years</td>
</tr>
</tbody>
</table>

REDUCED NICOTINE PRODUCTS MAY ENCOURAGE QUITTING

25% of participants who were originally not interested in quitting spontaneously quit smoking 4 weeks after completing the study.

SOME TOXIC AND CARCINOGENIC CONSTITUENTS VARY WIDELY IN PRODUCTS

Higher tobacco-specific nitrosamines in U.S. cigarettes increase the level of exposure.

Rates for squamous cell carcinoma are similar for men in the United States and Canada [2]. However, Canadian male adenocarcinoma incidence rates remain lower than those for squamous cell and are well below the adenocarcinoma incidence for White men in the United States [2].

VOLATILE ORGANIC COMPOUNDS CAN BE REDUCED BY USING CHARCOAL IN THE FILTER

TOBACCO pH ALTERS THE RELATIVE LEVELS OF THE FORMS OF NICOTINE
SMOKELESS UNPROTONATED (FREE) NICOTINE DELIVERY IS CONTROLLED THROUGH pH OF THE PRODUCT

RESEARCHING SCIENTIFIC PRIORITIES

• Diversity of Tobacco Products
• Reducing Addiction
• Reducing Toxicity and Carcinogenicity
• Adverse Health Consequences
• Communications
• Marketing of Tobacco Products
• Economics and Policies
THANK YOU