The Harm Reduction Opportunity with Smokeless Tobacco Products

Global Forum on Nicotine – Keynote Speech

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Cigarette Smoking: A Significant Public Health Problem

Cigarette smoking causes about one of every five deaths annually in the U.S.

Cigarette smoking causes an estimated 480,000 deaths annually.

Smokers’ life expectancy is about 10 years shorter than nonsmokers’.

Source: http://www.cdc.gov/tobacco/data_statistics/fact_sheets/health_effects/tobacco_related_mortality/index.htm#cigs
Harm Reduction Opportunities

~40 MM
Adult Cigarette Smokers

~10 MM
Adult E-Vapor Consumers

~5 MM
Adult Smokeless Consumers

Note: Figures shown are U.S. Adult Tobacco Consumers
Source: 18+ATCT 12MM ending December 2017
Numbers may not foot due to rounding
Over Half of U.S. Adult Smokers Are Interested in Reduced-Risk Tobacco Products

Source: Based on ALCS analysis of PATH Wave 1 data Sept 12, 2013 – Dec 14, 2014; Response to question – “If a tobacco product made a claim that it was less harmful to health than other tobacco products, how likely would you be to use that product?”

- ~55% (~22MM Adult Smokers)
- 18% Very Likely
- 37% Somewhat Likely
- 19% Somewhat Unlikely
- 27% Very Unlikely

Source: Altria Client Services | Regulatory Affairs | Global Forum on Nicotine | 6/15/2018 | FINAL
Innovative Non-Combustible Product Platforms

Smokeless/Oral Tobacco-Derived Nicotine

E-Vapor

Heated Tobacco
# Misperceptions about the Risks of Smokeless Tobacco (ST) vs. Cigarettes

Over 90% of cigarette smokers think ST* is about the same or more harmful than cigarettes

<table>
<thead>
<tr>
<th>% of adult cigarette smokers thinking each product is about the same harm as cigarettes</th>
<th>% of adult cigarette smokers thinking each product is more harmful than cigarettes</th>
</tr>
</thead>
<tbody>
<tr>
<td>Smokeless Tobacco</td>
<td>63.8%</td>
</tr>
<tr>
<td>Traditional Cigars</td>
<td>58.4%</td>
</tr>
<tr>
<td>E-Cigarettes</td>
<td>39.6%</td>
</tr>
</tbody>
</table>


*ST defined as loose snus, moist snuff, dip, spit or chewing tobacco.
USSTC Submits MRTP Application (MRTPA)

- MRTPA Submitted 3/20/18
- 365 Day Review Period from FDA filing
- Tobacco Products Scientific Advisory Committee (TPSAC) meeting
Linked Mortality Analysis:
Based on Nationally Representative Epidemiology

National Health Interview Survey
- Survey Years: 1987 – 2005 (intermittent)
- ~155,000 total respondents
  - ~3,000 smokeless tobacco users

National Longitudinal Mortality Study
- Based on the Current Population Survey
- Survey years: 1993-2005
- ~231,000 total respondents
  - ~3,500 smokeless tobacco users

Two nationally representative public health surveys linked to the National Death Index (2011 update)*

*Mortality outcomes available through linkage to the National Death Index (NDI)
available from the National Center for Health Statistics

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## Major Causes of Mortality

<table>
<thead>
<tr>
<th>Mortality outcome</th>
<th>Current Cigarette Smokers</th>
<th>Current Smokeless Tobacco Users</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>NEVER USED TOBACCO</td>
<td>NEVER USED TOBACCO</td>
</tr>
<tr>
<td>All causes</td>
<td><img src="chart1.png" alt="Graph" /></td>
<td><img src="chart2.png" alt="Graph" /></td>
</tr>
<tr>
<td>Diseases of the heart</td>
<td><img src="chart3.png" alt="Graph" /></td>
<td><img src="chart4.png" alt="Graph" /></td>
</tr>
<tr>
<td>Malignant neoplasms</td>
<td><img src="chart5.png" alt="Graph" /></td>
<td><img src="chart6.png" alt="Graph" /></td>
</tr>
</tbody>
</table>

### Graphs:

- **HAZARD RATIO**
  - **NHIS (N=36,090)**
  - **NLMS (N=38,076)**
- **NHIS (N=1,562)**
- **NLMS (N=1,863)**
### Specific Cancer Mortality (NHIS)

#### Mortality outcome

<table>
<thead>
<tr>
<th>Mortality outcome</th>
<th>Current Smokers vs. Never Smokers&lt;sup&gt;1&lt;/sup&gt;</th>
<th>Current ST Users vs. Never ST Users&lt;sup&gt;2&lt;/sup&gt;</th>
</tr>
</thead>
<tbody>
<tr>
<td>Esophagus</td>
<td><img src="Esophagus.png" alt="Graph" /></td>
<td><img src="Esophagus.png" alt="Graph" /></td>
</tr>
<tr>
<td>Pancreas</td>
<td><img src="Pancreas.png" alt="Graph" /></td>
<td><img src="Pancreas.png" alt="Graph" /></td>
</tr>
<tr>
<td>Oral cavity, lip and pharynx</td>
<td><img src="OralCavity.png" alt="Graph" /></td>
<td><img src="OralCavity.png" alt="Graph" /></td>
</tr>
<tr>
<td>Trachea, bronchus and lung</td>
<td><img src="Trachea.png" alt="Graph" /></td>
<td><img src="Trachea.png" alt="Graph" /></td>
</tr>
</tbody>
</table>

**HAZARD RATIO**

- **Current cigarette smokers (N=38,076)**
- **Current smokeless tobacco (ST) users (N=2,260)**

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<sup>1</sup> Estimates from NLMS public use data

<sup>2</sup> National Center for Healthcare Statistics suppresses cell sizes less than 5 to protect respondent confidentiality.
Summary

- Significant misperceptions exist regarding ST products among U.S. Adult Smokers despite the substantial risk differential
- Completely switching from cigarettes to ST presents a harm reduction opportunity
- Our MRTP application on Copenhagen® Fine Cut has the potential to:
  - Correct widely held misperceptions between smokeless tobacco and cigarettes
  - Help consumers make more informed tobacco product use decisions