The Harm Reduction Opportunity with Innovative Oral Tobacco-Derived Nicotine Products

Global Forum on Nicotine

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Agenda

- Current Situation
- VERVE® - Innovative Oral Tobacco Derived Nicotine Products
- ALCS Framework for Assessing Harm Reduction
  - Scientific Evidence
- Overall Conclusions
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
“We must recognize the potential for innovation to lead to less harmful products, which, under FDA’s oversight, could be part of a solution. While there’s still much research to be done on these products and the risks that they may pose, they may also present benefits that we must consider.”

Dr. Scott Gottlieb
FDA Commissioner
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?”

Numbers may not foot due to rounding.
Innovative Non-Combustible Product Platforms

- Oral Tobacco-Derived Nicotine
- E-Vapor
- Heated Tobacco
Innovative Oral Tobacco-Derived Nicotine Discs

- Flavor Varieties: Blue Mint & Green Mint
- VERVE® Discs contain:
  - USP Grade Tobacco-Derived Nicotine
  - Food Grade Ingredients
  - Biocompatible Medical Grade Polymer
- ~1.5mg of nicotine per Disc
- 16 Discs per child resistant package
VERVE® Chews Product Overview

Innovative Oral Tobacco-Derived Nicotine Chews

- Flavor Varieties: Blue Mint & Green Mint
- VERVE® Chews contain:
  - USP Grade Tobacco-Derived Nicotine
  - Food Grade Ingredients
- ~1.5mg of nicotine per Chew
- 12 Chews per child resistant package
Percent Reduction in HPHC levels of VERVE® Products Compared to Cigarettes in Market

- Nicotine (total): 41%
- NNK: >99%
- NNN: >99%
- (a)P*: >93%
- Cadmium: >99%
- Formaldehyde: >99%
- Acetaldehyde: >99%
- Crotonaldehyde: >99%
- Arsenic**: >99%

* (a)P levels were below detection limit of 2.0 ng/portion

**Arsenic levels were higher only in VERVE® Chews products compared to levels in cigarettes. These levels were lower than those found in Nicorette® gum.

Source: Percent reduction calculated based on maximum HPHC levels for different VERVE® products, relative to average HPHC levels for Marlboro® 100’s Box smoked under Health Canada smoking conditions (Oldham et al., 2014).

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Continued Decline of CPD When Switching to VERVE® Products

- **50-99% Reduction at Week 6 (n=202/517)**
- **No Cigarettes at Week 6 (n=120/517)**

- **50-99% Reduction at Week 12 (n=76/410)**
- **No Cigarettes at Week 12 (n=17/410)**

Average number of CPD

Source: VERVE® Discs or Chews Actual Use Study - ALCS-CMI-17-22-VRV

Source: VERVE® Blue Mint Discs 12-Week Extended Home Use Test – ALCS-CMI-eHUT-12-V1

CPD = Cigarettes per day
Overall Conclusions

- Over half of U.S. Adult Smokers are interested in reduced-risk tobacco products

- We have a robust framework to develop and evaluate our oral tobacco products to demonstrate harm reduction

- Innovative oral tobacco-derived nicotine products present an opportunity to reduce the harm from cigarette smoking