

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



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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'

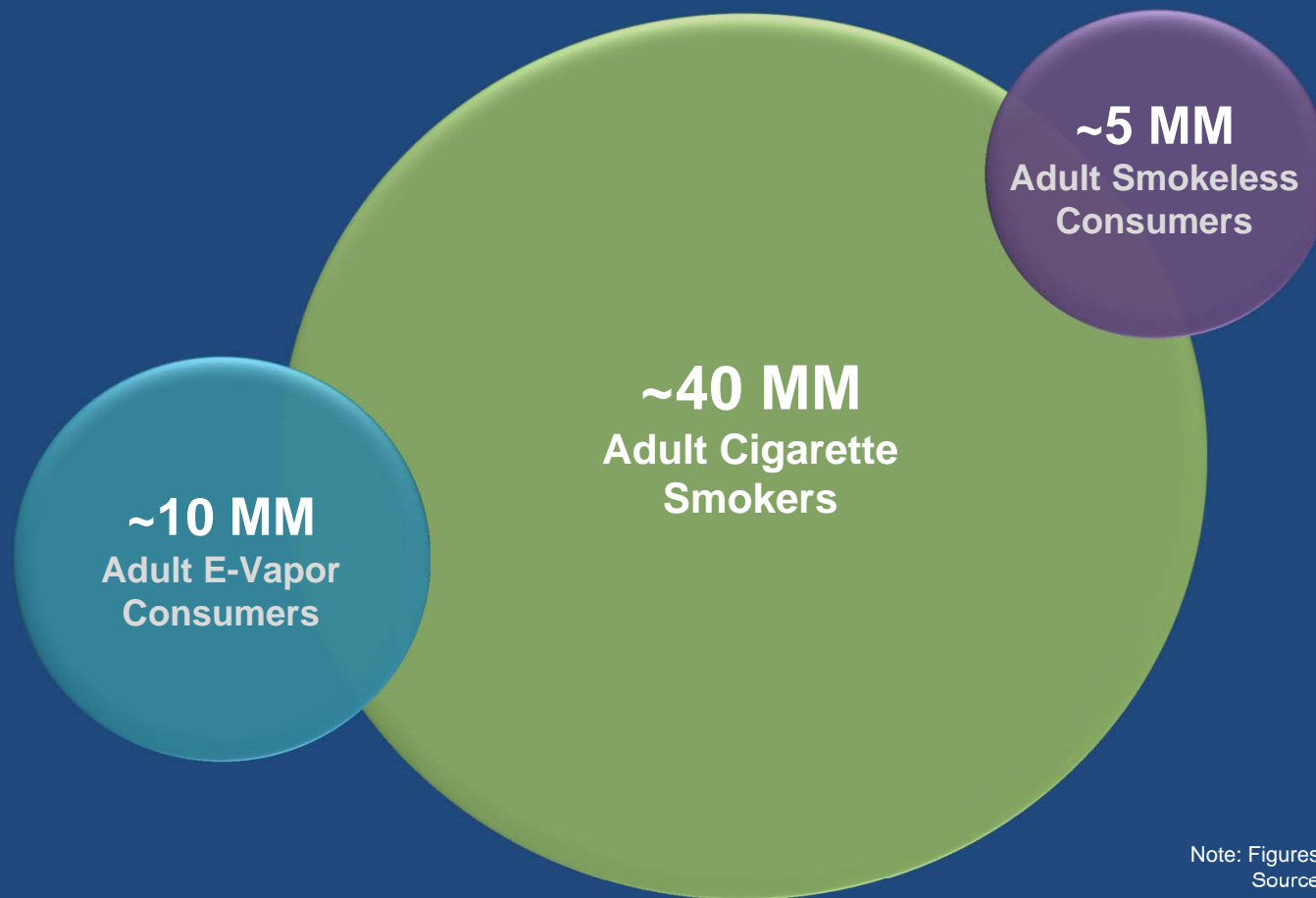
Source: http://www.cdc.gov/tobacco/data_statistics/fact_sheets/health_effects/tobacco_related_mortality/index.htm#cigs



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Harm Reduction Opportunities



Note: Figures shown are U.S. Adult Tobacco Consumers
Source: 18+ATCT 12MM ending December 2017
Numbers may not foot due to rounding



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FDA Recognizes Continuum of Risk

“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

Combusted
Tobacco Products

Most Harmful

Non-combusted
Tobacco Products

Least Harmful



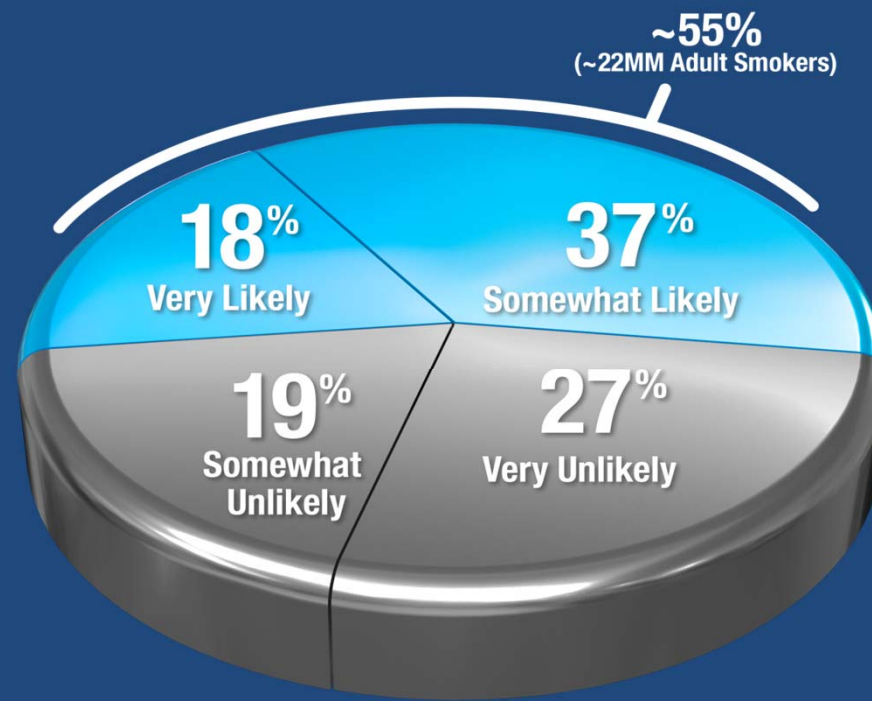
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July 28, 2017: Protecting American Families: Comprehensive Approach to Nicotine and Tobacco
<https://www.fda.gov/NewsEvents/Speeches/ucm569024.htm>

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Over Half of U.S. Adult Smokers Are Interested in Reduced-Risk Tobacco Products



Numbers may not foot due to rounding

Source: Based on ALCS analysis of PATII 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?”



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Innovative Non-Combustible Product Platforms

Oral Tobacco-Derived Nicotine



E-Vapor



Heated Tobacco



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VERVE® Discs Product Overview

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



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VERVE® Chews Product Overview

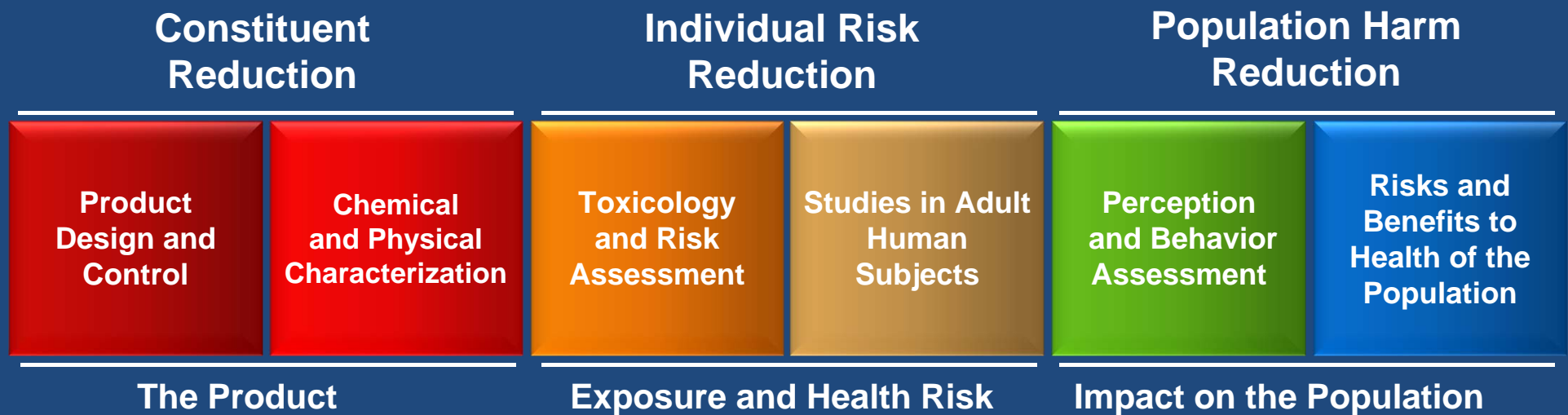
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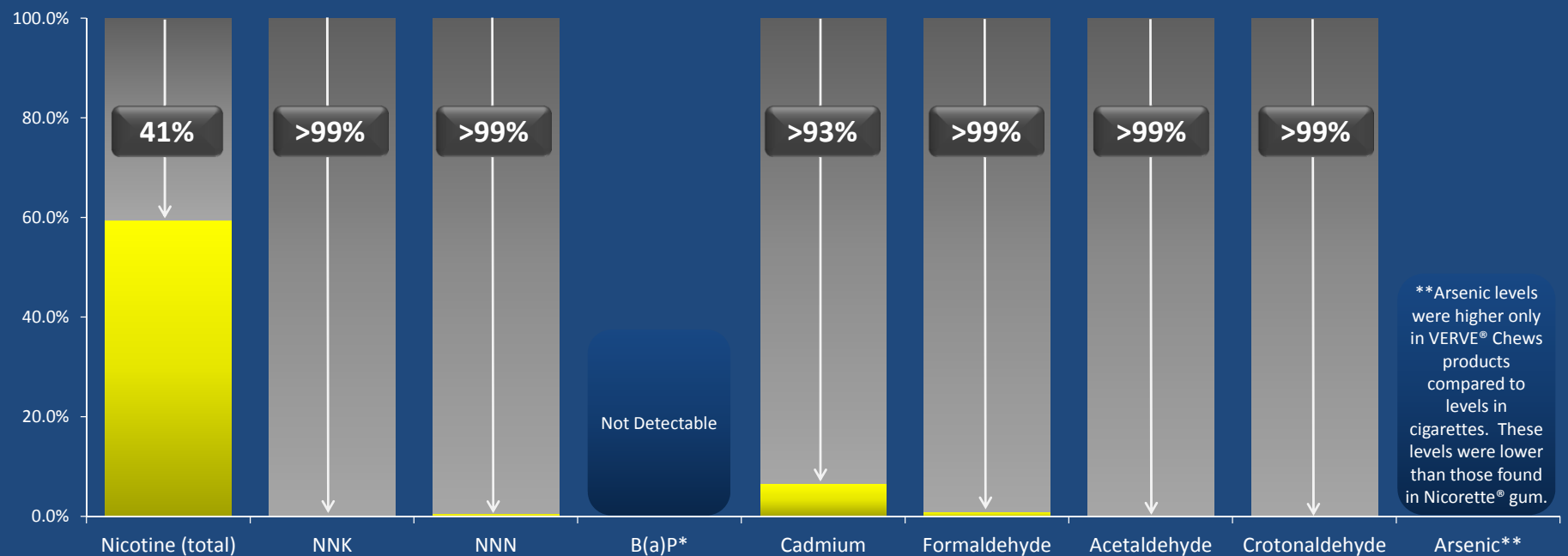
ALCS Reduced Harm Evaluation Framework



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Percent Reduction in HPHC levels of VERVE® Products Compared to Cigarettes in Market



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

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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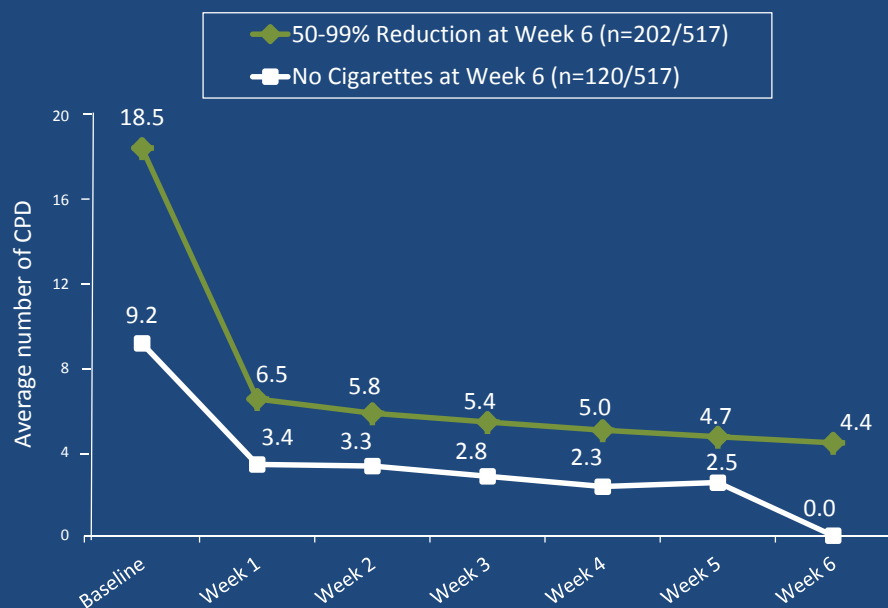
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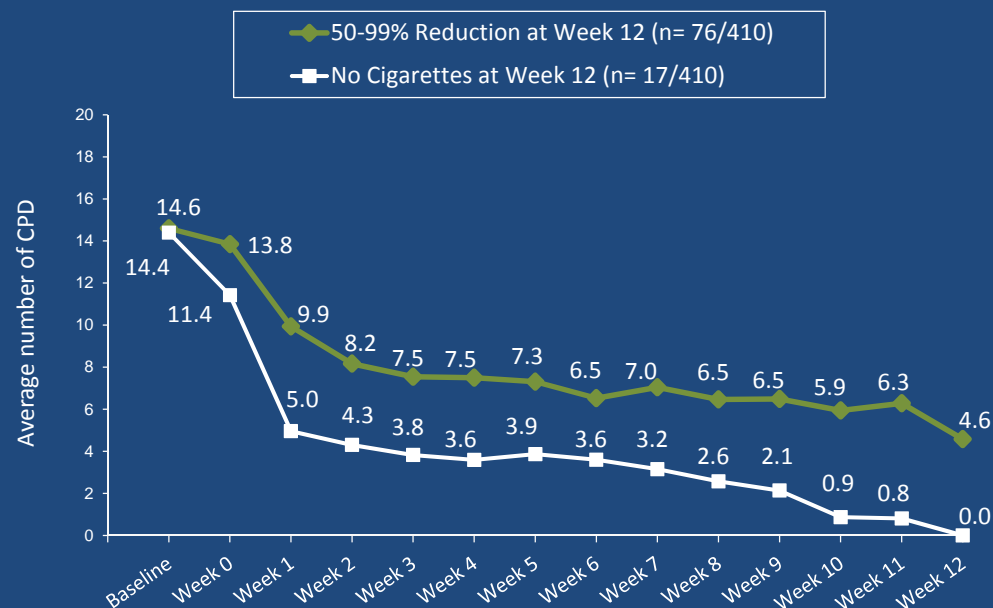
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Continued Decline of CPD When Switching to VERVE® Products



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



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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



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