

The Harm Reduction Potential of Oral Tobacco Derived Nicotine Products

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— FAMILY OF COMPANIES —



Agenda



The Problem: Cigarettes

Altria's Approach to Harm Reduction

Harm Reduction Potential of OTDN

Barriers to Advancing Harm Reduction



Harm Caused from Cigarette Smoking

COMBUSTIBLE TOBACCO – MOST HAZARDOUS FORM OF TOBACCO



30.8MILLION
US adult smokers¹

**OVERWHELMING
EVIDENCE**

**Cigarette smoking is addictive and
causes serious diseases including:**

Lung cancer | Emphysema | Cardiovascular disease

~443,000 U.S. Deaths Attributable Each Year to Cigarette Smoking*



¹Tobacco product use among adults – United States 2020. MMWR March 2022; 71 (11) 397-405.

*Average annual number of deaths, 2000-2004.





Tobacco Harm Reduction Framework

**Traditional
Strategies**



**Complement to
Existing Approach**



**Tobacco
Harm
Reduction
Framework**

ATC=Adults Tobacco Consumers

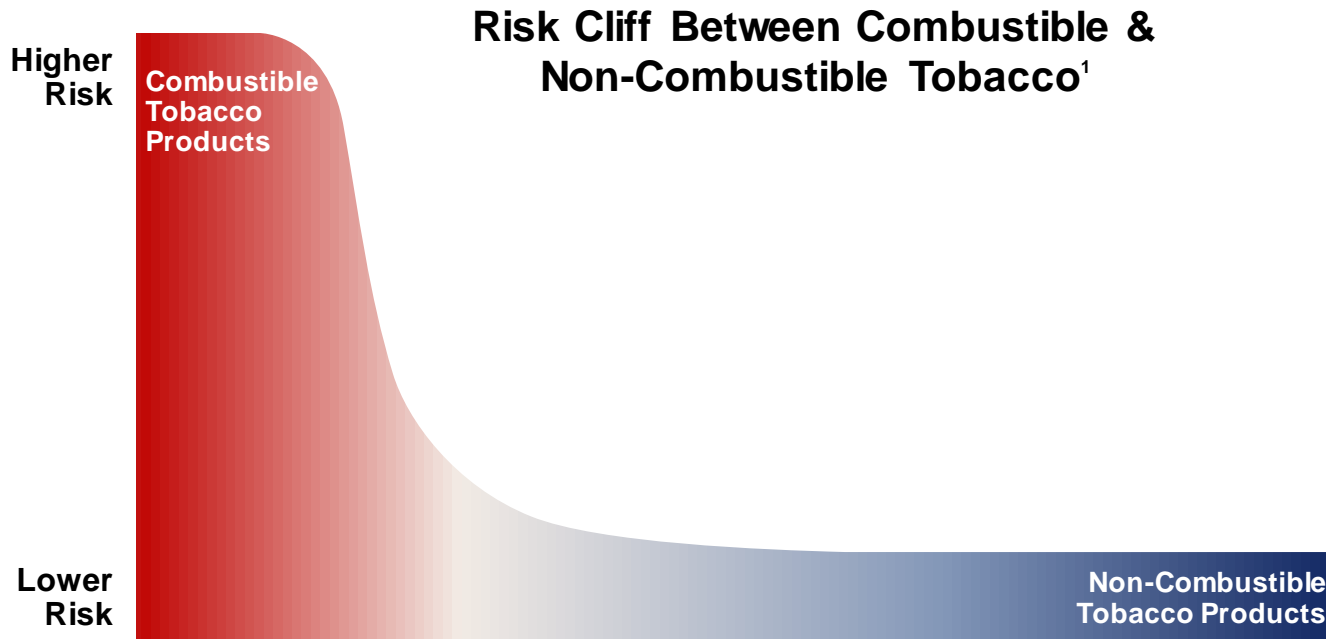


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Moving Adults Who Smoke Down the “Risk Cliff”



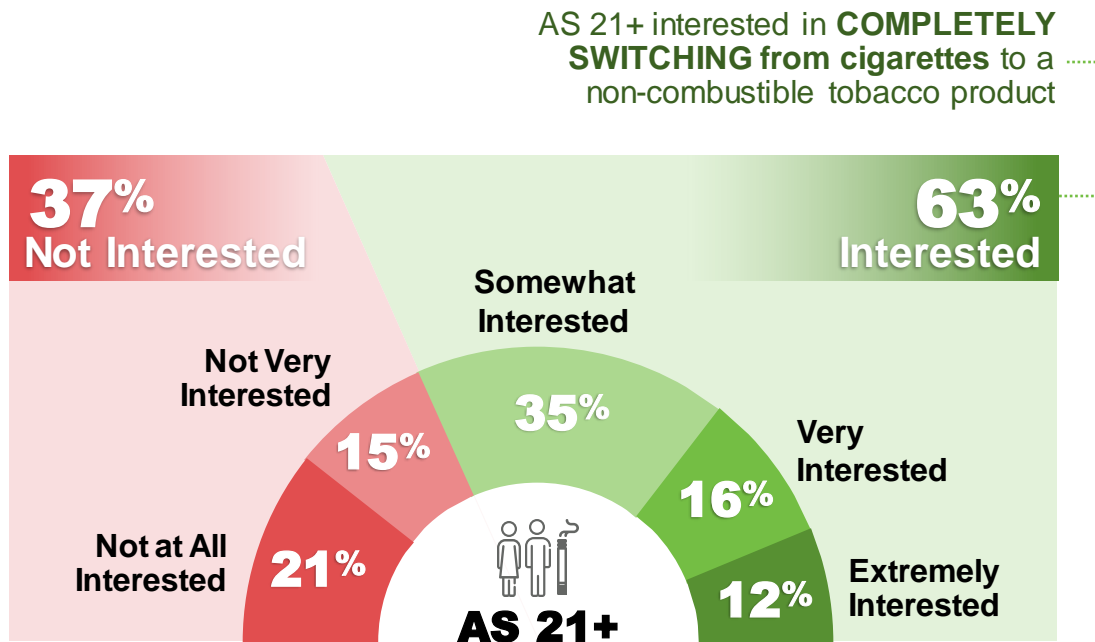
¹Adapted from Nutt, et. al. Estimating the Harms of Nicotine-Containing Products Using the MCDA Approach. Eur. Addict Res 2014; 20:218-225.



There is Interest Among Adults 21+ Who Smoke (AS) in Completely Switching to Non-combustibles

? **AS 21+**
n=1596

In the next 6 months, how interested are you in **completely switching** all of your current cigarette usage occasions to a different tobacco product (such as e-vapor, smokeless tobacco, snus or nicotine pouches)?



Source: ALCS CMIII Tobacco Product Portfolio Study Phase 1 (2021).



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The Problem: Cigarettes

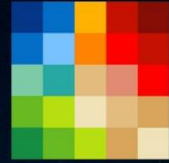
Altria's Approach to Harm Reduction

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Moving beyond smoking™



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Responsibly lead
the transition of adult smokers to a
SMOKE-FREE FUTURE

A Portfolio Approach to Harm Reduction

Advance Altria's harm reduction aspiration through smoke-free product platforms



**Smokeless
Tobacco Products**
e.g., Copenhagen®

**Heated
Tobacco Products**
e.g., PLOOM®*

**Oral Tobacco-
Derived Nicotine
Products**
e.g., on!® Nicotine Pouches

**E-Vapor
Products**
e.g., NJOY



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*PLOOM® is currently unavailable for sale in the United States.

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Reduced
Harm

Adult Tobacco
Consumer Interest
& Use

Accurate
Communications

Barriers to Advancing Harm Reduction



on!® Harm Reduction Opportunity

on!® nicotine pouches have the most variety of any nicotine pouches currently in the U.S. Market



All flavors are available for purchase through e-commerce. Select SKUs are available in retail.



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Scientific Framework

CONSTITUENT REDUCTION



THE PRODUCT

- Chemistry Manufacturing and Controls
- Product Stability
- Harmful or Potentially Harmful Constituents (HPHC)

INDIVIDUAL RISK REDUCTION



EXPOSURE and HEALTH RISK

- Health risk assessment (absolute and relative)
- Chemical Analyses
- Human Studies
- Human Factors Assessment
- Risk Assessment

POPULATION HARM REDUCTION



IMPACT on the POPULATION

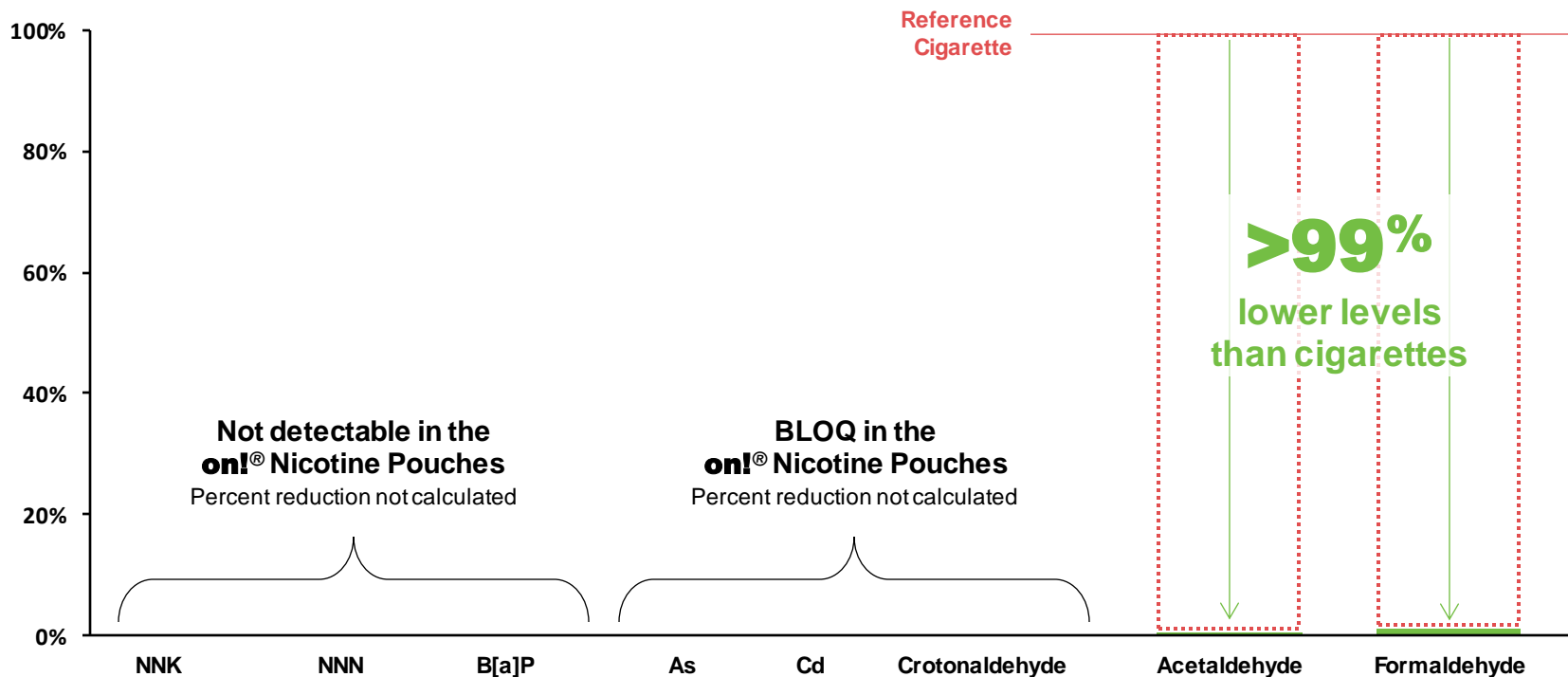
- Risk perceptions (absolute and relative)
- Impact of product on users
- Impact on non-users
- Overall impact on the population
- Environmental Assessment



HPHCs in on!® Nicotine Pouches are Absent or Substantially Reduced Compared to Cigarettes



CONSTITUENT REDUCTION



As=Arsenic; B[a]P=Benzo[a]pyrene; BLOQ=Below Limit of Quantitation; Cd=Cadmium; HPHC=Harmful or Potentially Harmful Constituents; NNK=4-(methylnitrosamino)-1-(3-pyridyl)-1-butanone; NNN=N-nitrosornicotine.

Source: Percent reductions based on average HPHC levels in 4 mg on! Mint product compared to cigarette mainstream smoke levels measured under ISO conditions.



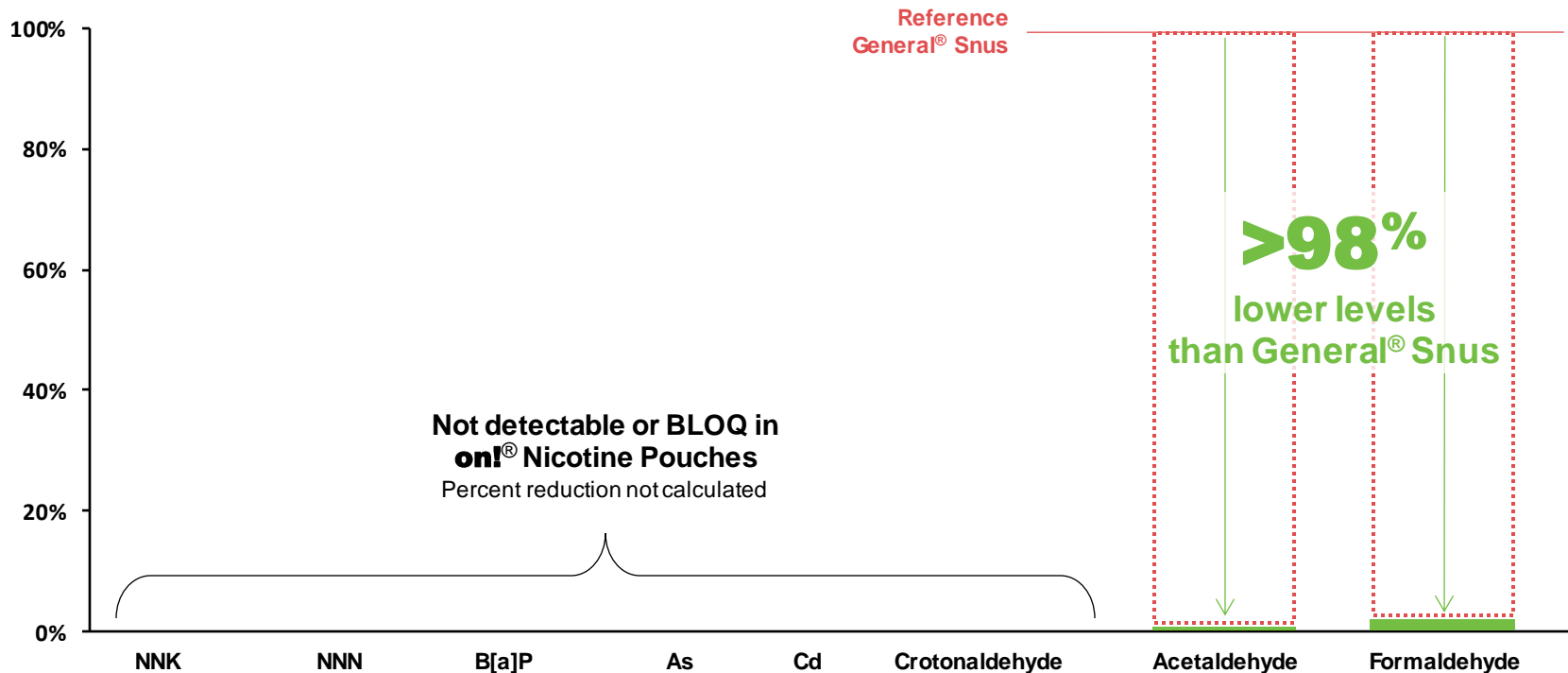
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HPHCs in on!® Nicotine Pouches are Absent or Substantially Reduced Compared to General® Snus



CONSTITUENT REDUCTION



As=Arsenic; B[a]P=Benzo[a]pyrene; BLOQ=Below Limit of Quantitation; Cd=Cadmium; HPHC=Harmful or Potentially Harmful Constituents; NNK=4-(methylnitrosamino)-1-(3-pyridyl)-1-butanone; NNN=N-nitrosonornicotine.

Source: Percent reductions based on average HPHC levels in 4 mg on! Mint product compared to the average HPHC levels for the eight MRTP authorized General® Snus products.



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Risk Assessment of Non-Tobacco Ingredients Demonstrates Levels Below Acceptable Daily Intake



on!® and on! PLUS Nicotine Pouches contain tobacco derived nicotine, which meets European Pharmacopeia standards



Most ingredients are designated as “Generally Recognized as Safe” (GRAS) for use in food, beverages or chewing gum and are present at levels that result in human exposure deemed acceptable for use in foods



Toxicological risk assessment of non-tobacco ingredients is based on published clinical and nonclinical literature

Our Risk Assessment of Non-Tobacco Ingredients indicates
**Exposure is Below Acceptable Daily Intake Values
as Established by Authoritative Bodies***

*e.g., JECFA (Joint Economic Committee of the WHO/FAO on Food Additives), EFSA (European Food Safety Authority), US FDA.



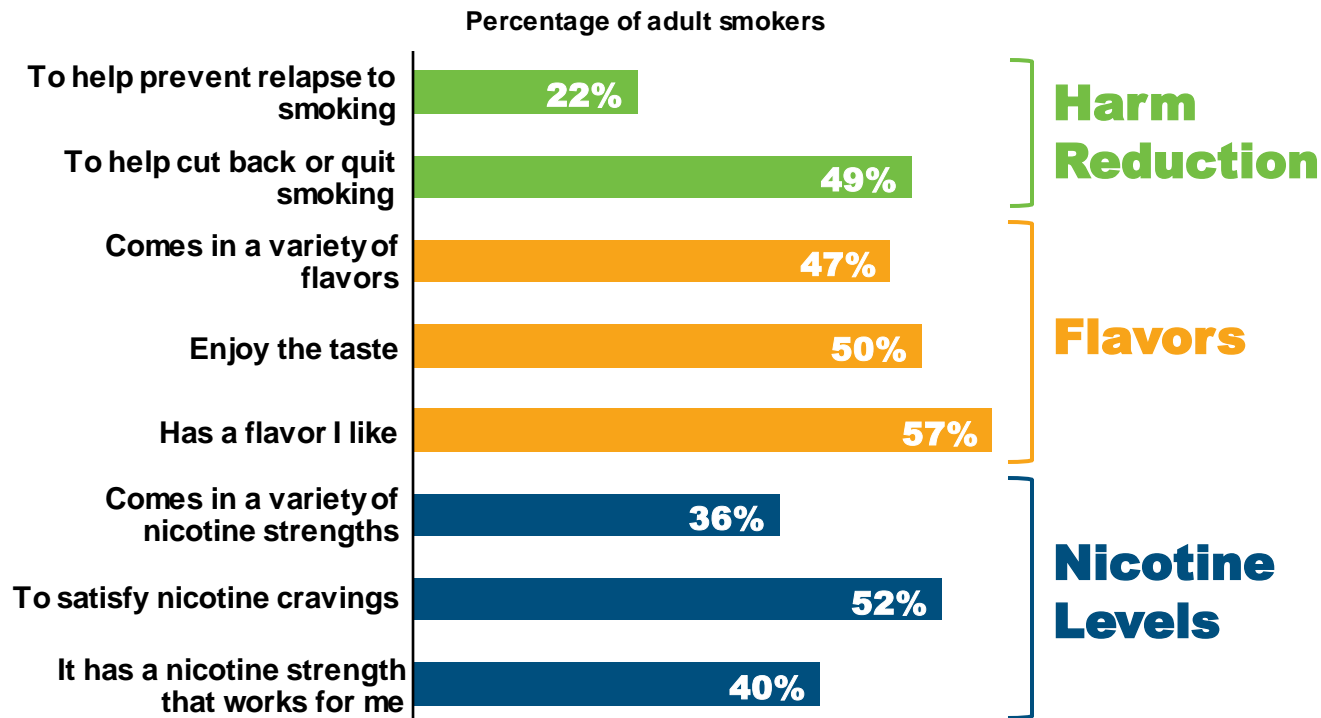
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Reasons for Future Use of on!® Among Adults Who Smoked



POPULATION HARM REDUCTION



Source: AUS Study Report and additional ALCS analysis



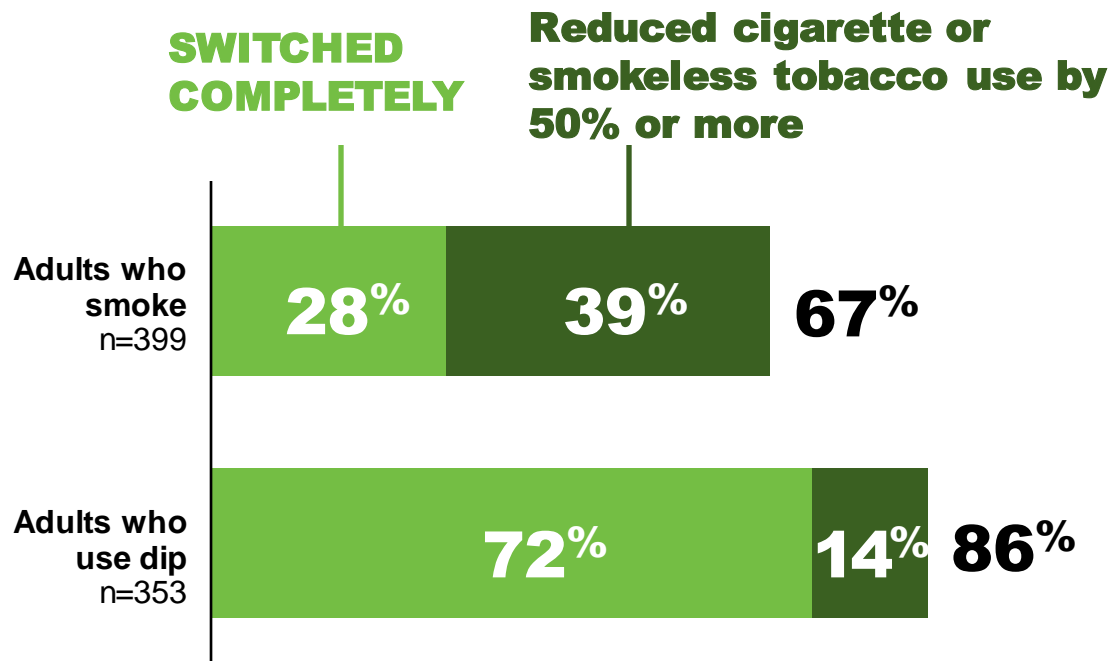
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Large Proportions of Adults Using Traditional Tobacco Switched or Reduced Consumption



POPULATION HARM REDUCTION



Source: AUS Study Report and additional ALCS analysis



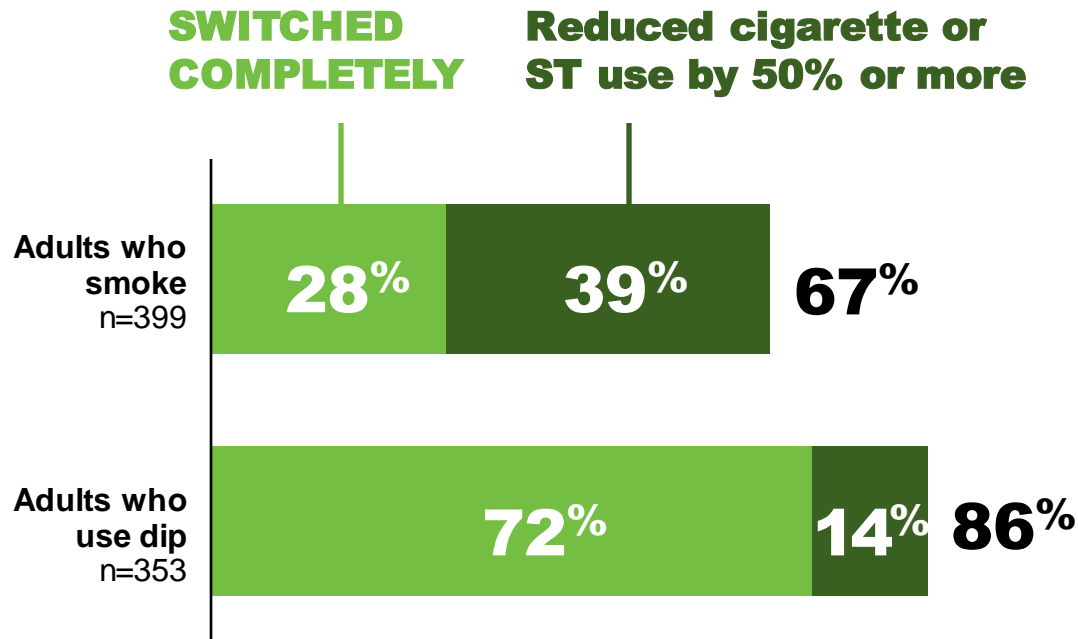
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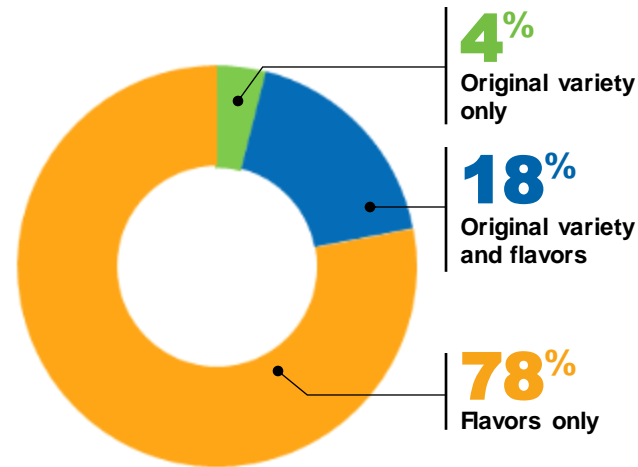
Large Proportions of Adults Using Traditional Tobacco Switched or Reduced Consumption



POPULATION HARM REDUCTION



Most switchers used flavored on!® nicotine pouches



ST=Smokeless Tobacco.

Source: AUS Study Report and additional ALCS analysis



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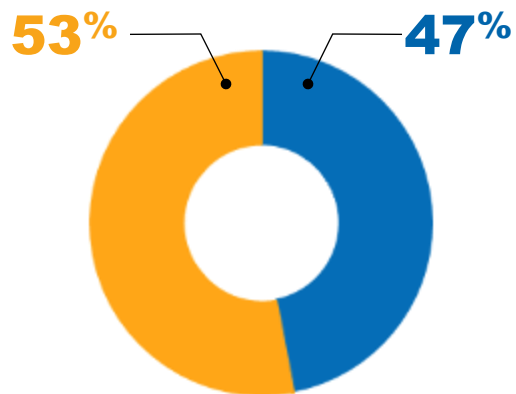
OTDN: Overall Preference for Flavored Varieties



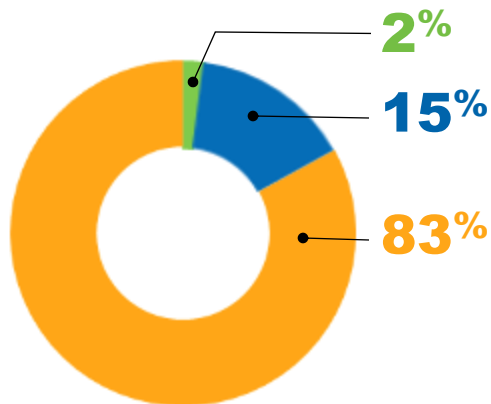
POPULATION HARM REDUCTION

■ Original Variety Only ■ Original Variety and Flavors ■ Flavors Only

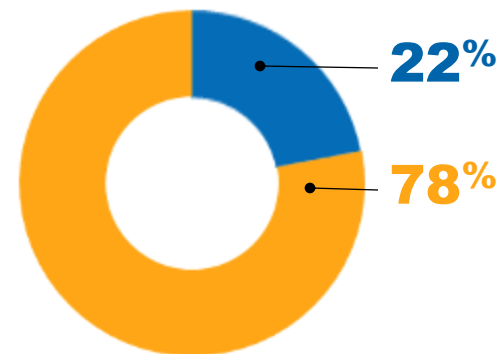
Varieties Used
Over 6 Weeks



Varieties Used
During Week 6



Purchase Interest
Week 6



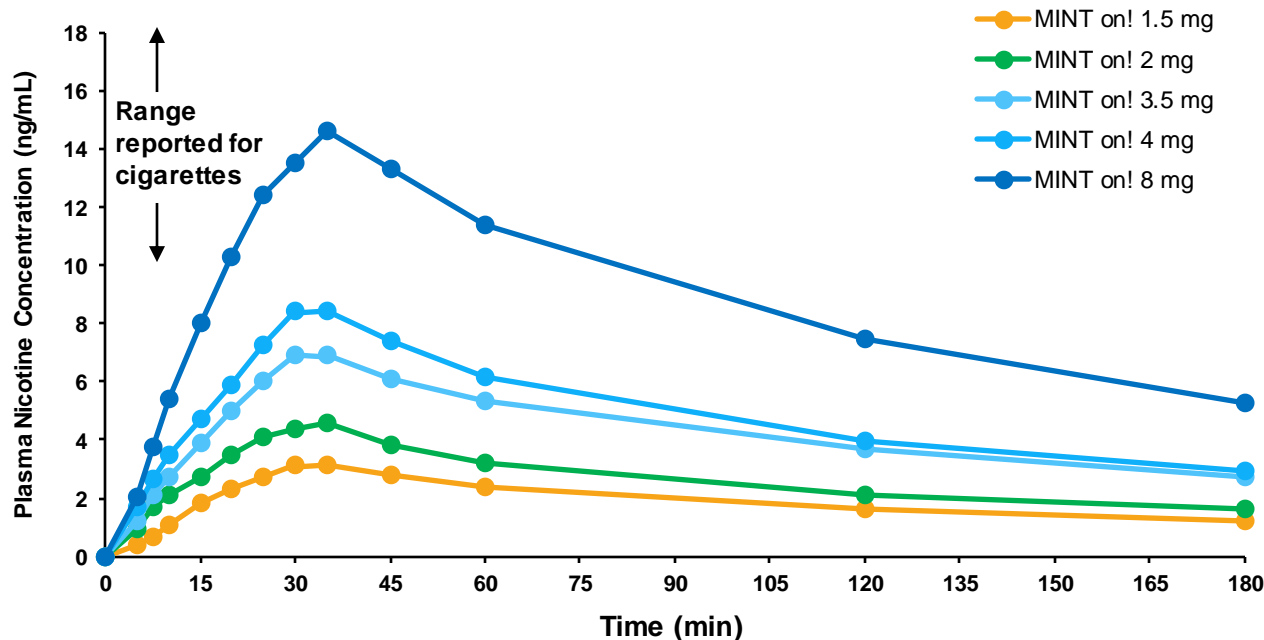
Source: AUS Study, Additional ALCS analysis.



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The on!® Portfolio Delivers a Wide Range of Nicotine



“[i]deally, a [reduced risk tobacco product] would be sufficiently reinforcing so as to attract smokers away from conventional cigarettes but not encourage the widespread dependent use of the product by individuals who were previously nonusers or who would have quit smoking.”

Institute of Medicine*, 2012
Scientific Standards for Studies on
Modified Risk Tobacco Products

*Approximate range of historical average peak levels (own brand cigarette on!® use: 1 pouch placed between the upper lip and gum for 30 min, study conducted in subjects that use cigarettes and MST (ALCS-REG-19-13-OTDN)



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Low Likelihood of Appeal and Use on!® Nicotine Pouches Among Nonusers of Tobacco Products

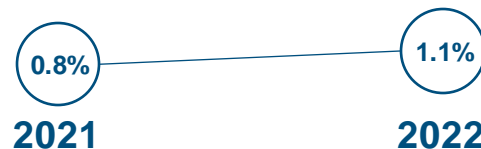
Low likelihood of appeal among nonusers and low intentions to try and use

Adult nonusers understand that the on!® products are not risk-free

Absolute risk perceptions are not lowered from exposure to marketing and advertising

Low likelihood of initiation by youth

Current (past 30-day) Nicotine Pouch Use Among Middle and High School Student Combined¹



¹Data from National Youth Tobacco Survey 2021 and 2022 – Nicotine pouch use \geq 1 day in the past 30 days.



Integration of Multiple Lines of Evidence to Demonstrate APPH*

- ✓ HPHC reduced / eliminated
- ✓ Switching will reduce exposure to most HPHCs, which should reduce smoking related disease risks
- ✓ Many adult smokers switch completely or reduce cigs \geq 50%
- ✓ Adult tobacco users perceive products not risk-free
- ✓ Abuse potential lower or comparable to cigarettes or ST
- ✓ Low likelihood of use among nonusers, including youth



Net Population Benefit

APPH

*Appropriate for the Protection of Public Health

HPHC=Harmful and Potentially Harmful Constituents; ST=Smokeless Tobacco.



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Most Adults in US Believe That Nicotine Causes Cancer



Contents lists available at [ScienceDirect](#)

Preventive Medicine 96 (2017) 94-100

journal homepage: www.elsevier.com/locate/ypmed



U.S. adults' addiction and harm beliefs about nicotine and low nicotine cigarettes

Erin Keely O'Brien, Anh B. Nguyen *, Alexander Persoskie, Allison C. Hoffman
Center for Tobacco Products, Food and Drug Administration, United States

“ About **three quarters** of people either were unsure of the relationship between nicotine and cancer or **incorrectly believed that nicotine causes cancer**. ”

“ Incorrect **beliefs that nicotine causes cancer** could **discourage smokers from switching** to safer nicotine containing alternatives. ”



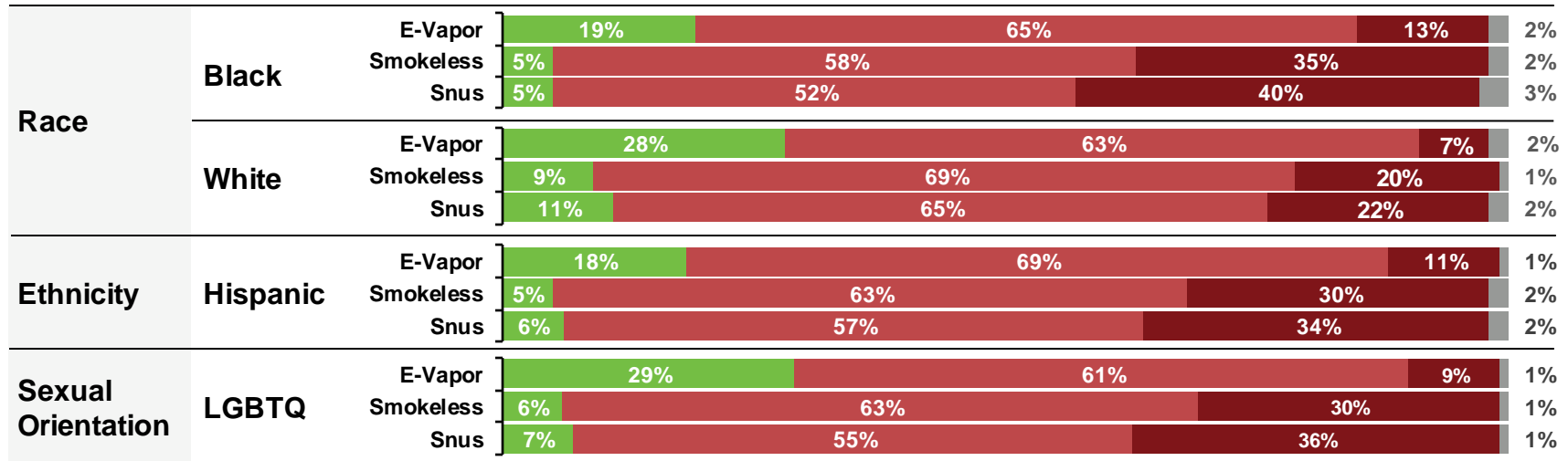
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A Majority of Adults Who Smoke Believe That Smoke-Free Products are About the Same or More Harmful Than Smoking

PATH Wave 4 (2018-2019) Data on Adults Who Smoke Cigarettes

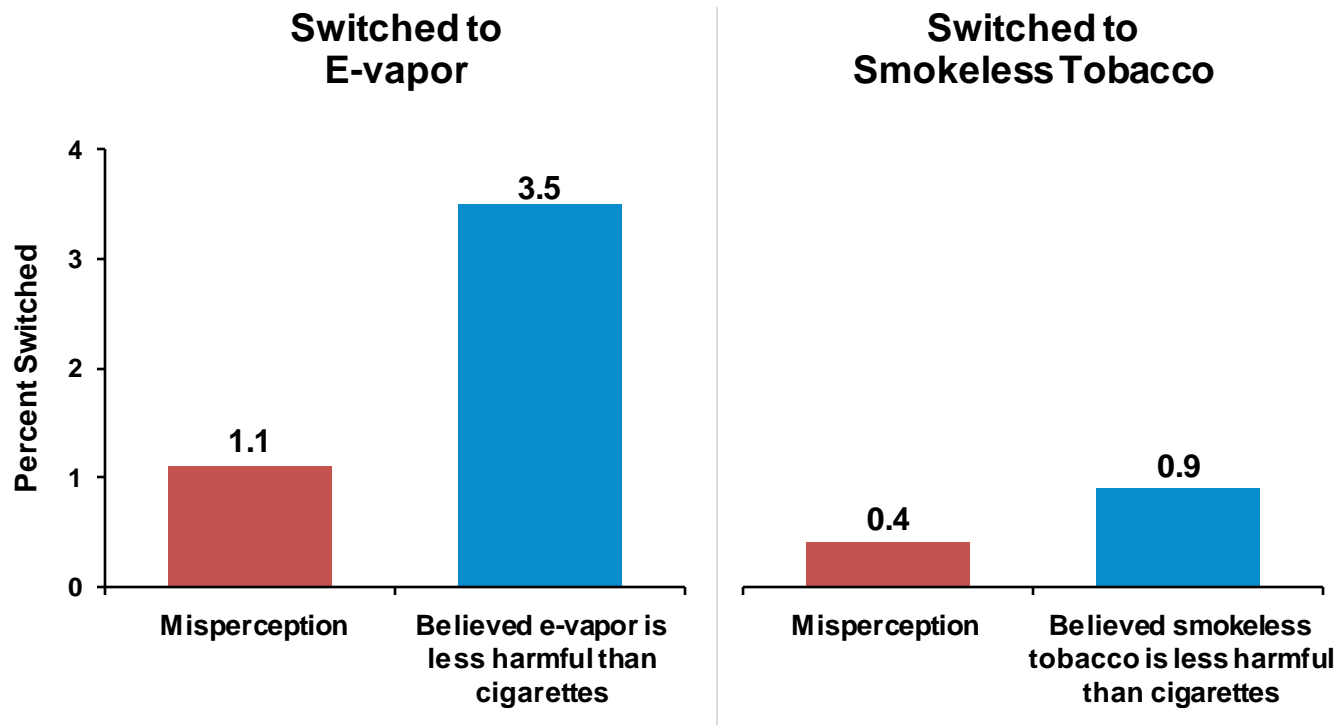
■ Less Harmful ■ About the Same ■ More Harmful ■ Don't Know



Perceived Harmfulness of Tobacco Products Compared to Smoking Cigarettes,
PATHWave 4 Adult Who Use Tobacco



Percent of Smokers Who Switched to E-Vapor or Smokeless Tobacco the Following Year



Smokers with an accurate perception of risk are

2-3x

MORE LIKELY TO SWITCH

Analysis includes adult smokers who stopped smoking and used either e-vapor or smokeless tobacco from PATH Wave 3 to Wave 4.



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Role of Public Health and Authoritative Bodies in Communicating Accurate Risk Information

People who smoke look to public health and authoritative bodies for credible information on tobacco products



The vast majority view doctors, health care organizations (i.e., AMA, ALA, etc.), public health organizations (i.e., FDA, HHS, etc.), and university scientists/researchers, as the **most trusted sources of information on tobacco harm reduction**.

More than **8 in 10** agree that **FDA has a responsibility to:**

89%

Accurately inform adult tobacco consumers about the different risks associated with different tobacco products.

86%

Inform the public about nicotine misperceptions, including the misperception that nicotine causes cancer.

81% agree that if certain tobacco products have been scientifically shown to be less risky than cigarettes, **physicians have a responsibility to communicate this information** to their patients who are adult tobacco consumers and have not successfully quit smoking by using traditional cessation therapies.



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Advancing Tobacco Harm Reduction



CHOICES

A variety of
FDA-authorized reduced-
risk products for adult
tobacco consumers



COMMUNICATION

Accurate, non-misleading
information about reduced
risk products and
consistent message from
public health authorities



CONSISTENCY

A consistent message
from public health
authorities in addition to
FDA-authorized claims
from manufacturers



on!® PLUS Harm Reduction Opportunity

on!® PLUS is a spit-free nicotine pouch product designed for adult dippers and dual users of dip and cigarettes

THREE FLAVORS



3 NICOTINE STRENGTHS

6
MG

9
MG

12
MG

Nicotine
pouches



NO TOBACCO LEAF

on!® PLUS is not available commercially; pending PMTA submission and FDA market authorization



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Any
Questions?

