

# Are Flavored Smoke-free Products Necessary? A Case Study on the Role of Flavors in Switching Behavior Among Adults Who Smoke

Elizabeth Becker, Jennifer Lewis, Mohamadi Sarkar  
*Regulatory Affairs*



Altria

— FAMILY OF COMPANIES —





## Background: Tobacco Use and Flavors

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### Case Study: *on!*<sup>®</sup> Nicotine Pouches

Intentions &  
Appeal

Use &  
Consumption

Behavioral  
Outcomes

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## Underage Use of Smoke-free Products





## **Background: Tobacco Use and Flavors**

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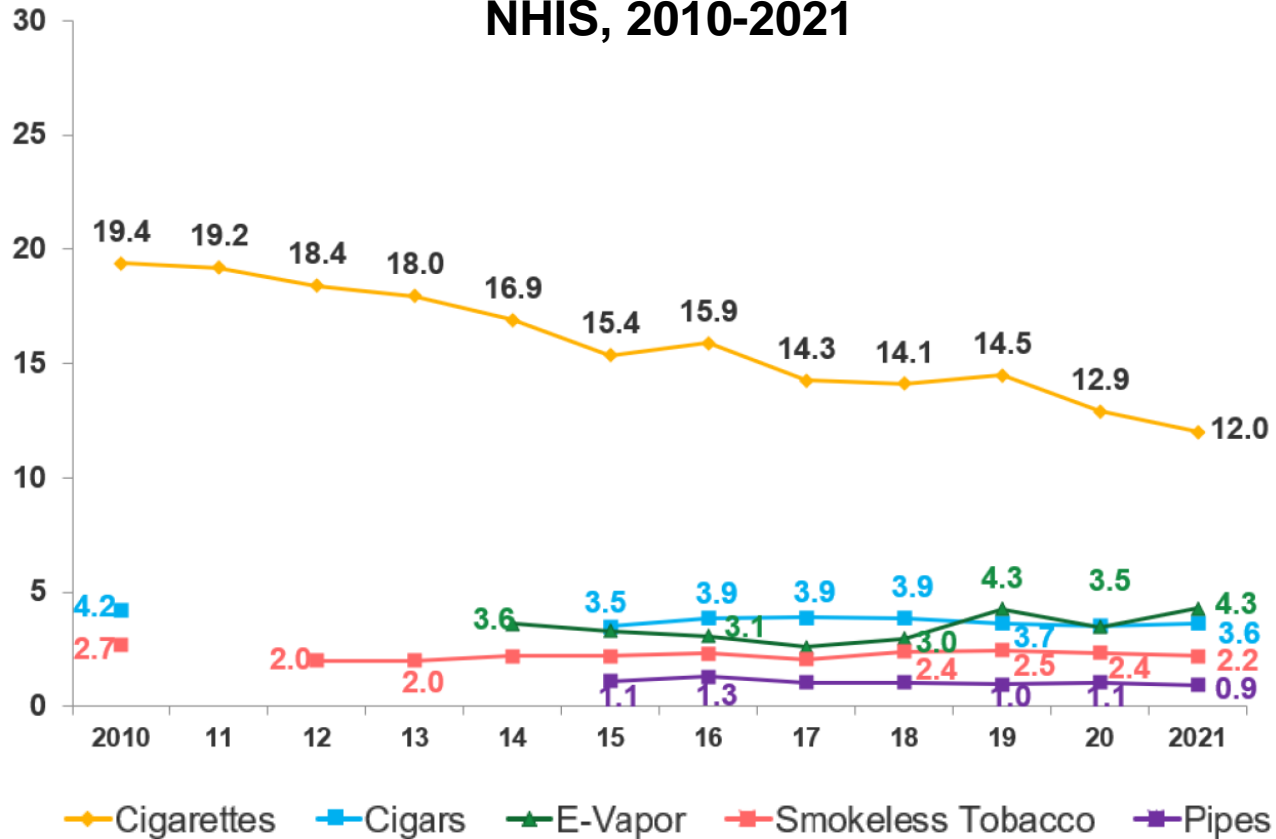
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### **Underage Use of Smoke-free Products**

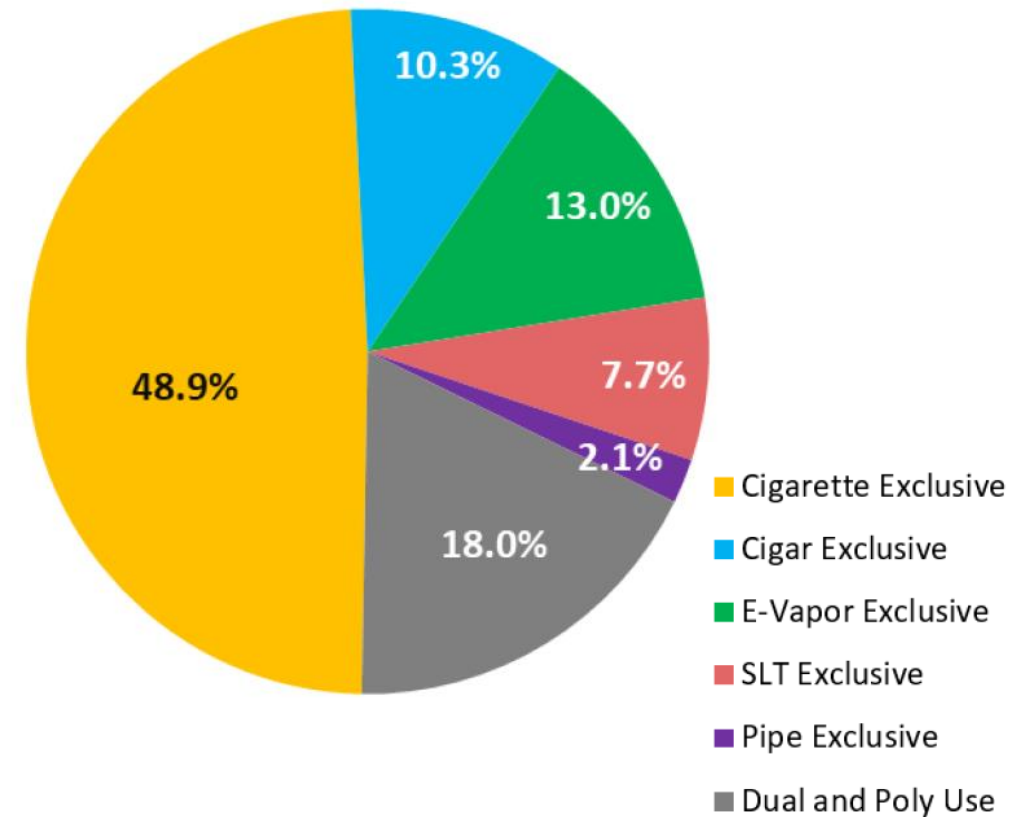


# Cigarette Smoking is at an All-Time Low Among Adults but Still Most Common Form of Tobacco Use

**% of Current (Every Day or Some Days) Tobacco Use  
NHIS, 2010-2021**



**% of Exclusive, Dual and Poly Use  
Among Current Tobacco Users  
NHIS, 2021**



NHIS – National Health Interview Survey, 2021: <https://www.cdc.gov/nchs/nhis/>  
SLT: Smokeless Tobacco

# Tobacco Harm Reduction Framework

**Traditional Strategies**



**Complement to Existing Approach**



**Tobacco Harm Reduction Framework**

ATC=Adult Tobacco Consumers



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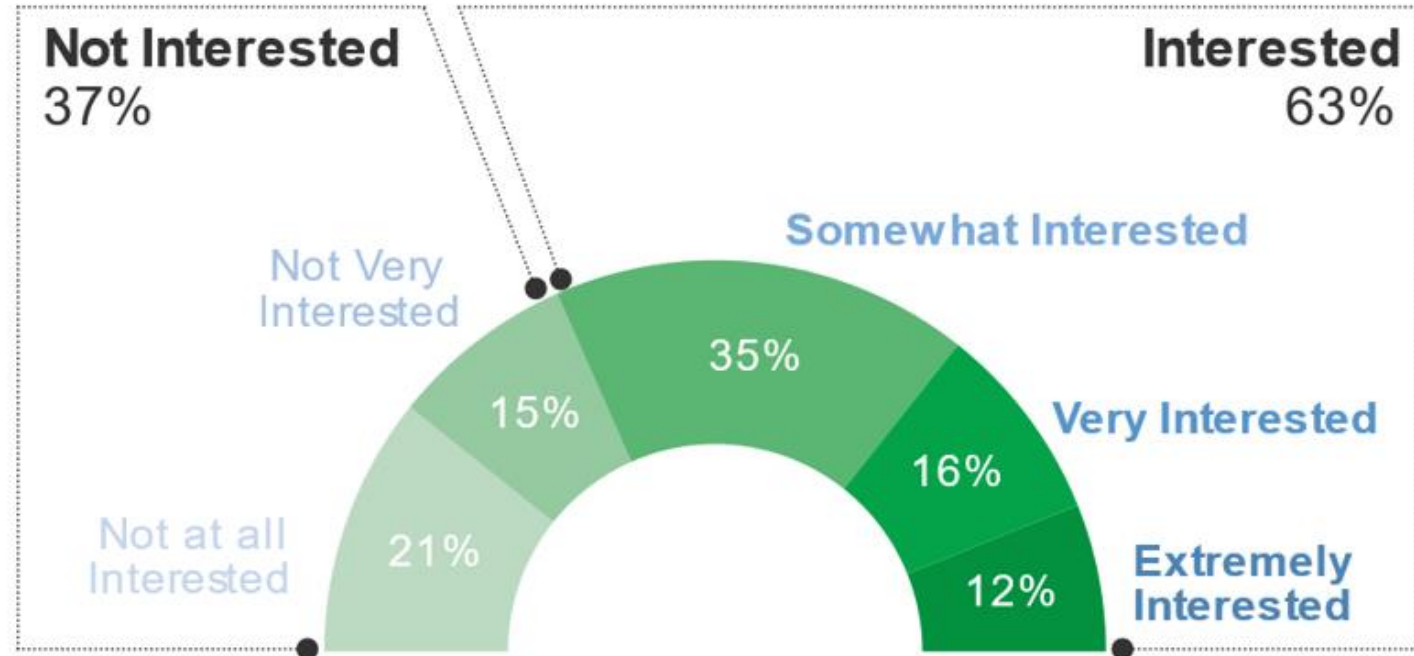
# There is Interest Among Adults 21+ Who Smoke (AS) in Completely Switching to Non-combustibles



AS 21+  
n=1596

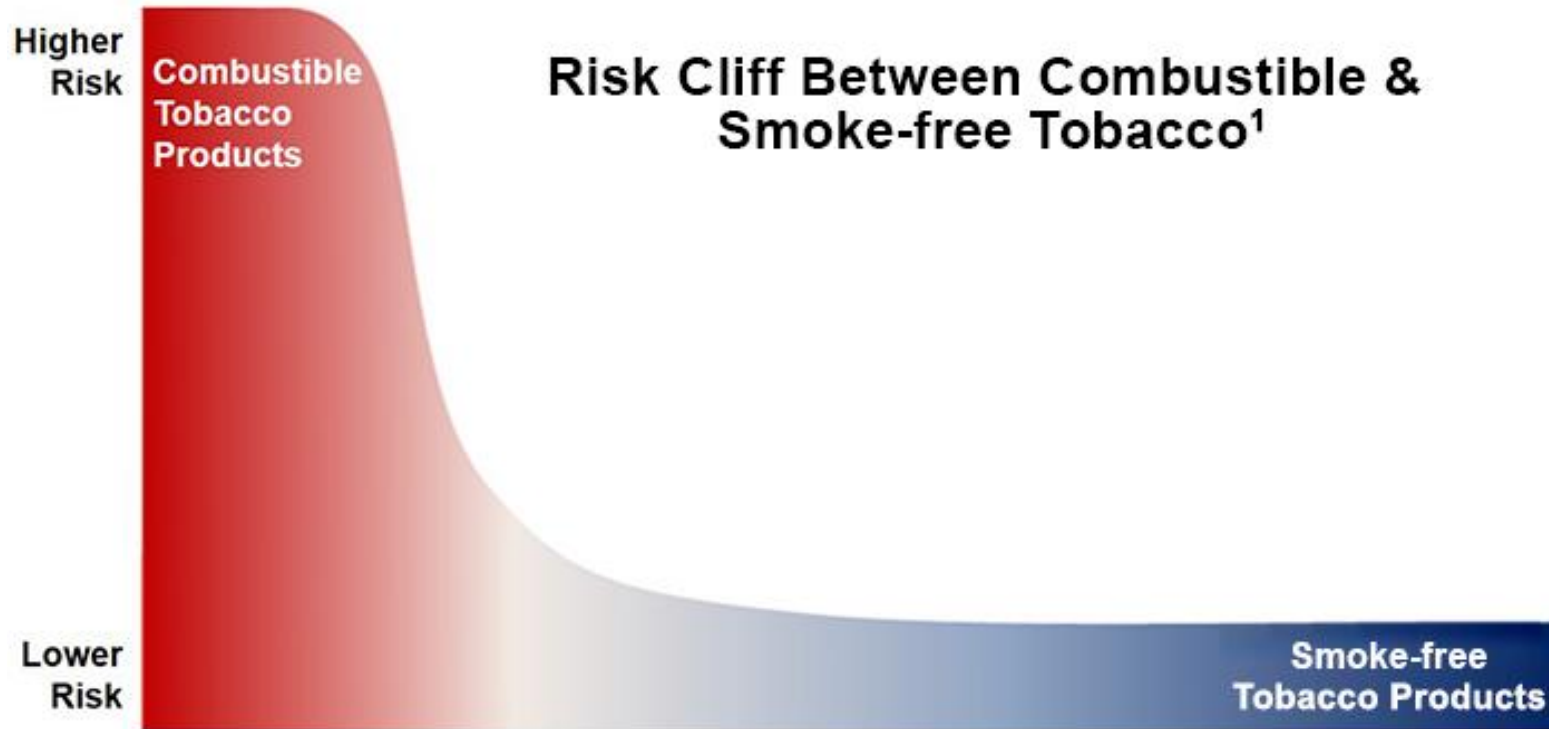
In the next 6 months, how interested are you in **completely switching** all of your current cigarette usage occasions to a different tobacco product (such as e-vapor, smokeless tobacco, snus or nicotine pouches)?

**63%** AS 21+ interested in **COMPLETELY SWITCHING** from cigarettes to a non-combustible tobacco product



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

# Moving Adults Who Smoke Down the “Risk Cliff”



*“[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.”*

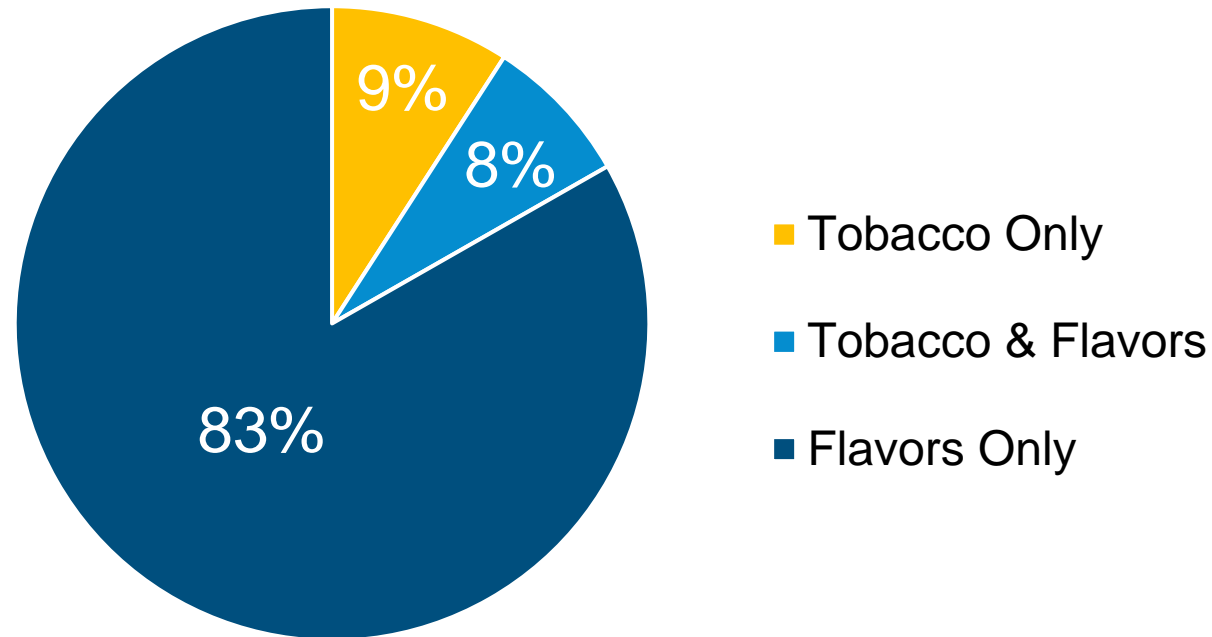
Institute of Medicine\*, 2012.  
Scientific Standards for Studies on  
Modified Risk Tobacco Products.

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

\* Now the National Academy of Medicine

# Majority of AS Who Transitioned to Exclusive E-Vapor Used Flavored E-Vapor Products

Wave 4 Use of Tobacco-Flavored or Other Flavor Varieties of E-Vapor among Adult Smokers Who Transitioned from Dual Use (Wave 4) to E-Vapor Product Use (Wave 5)



Source: The Population Assessment of Tobacco and Health (PATH) Study (<https://pathstudyinfo.nih.gov/>)  
ALCS Analysis Wave 4 and Wave 5 data





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## Underage Use of Smoke-free Products



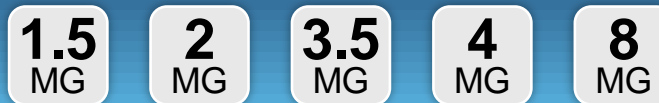
# on!<sup>®</sup> Harm Reduction Opportunity

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

## SEVEN VARIETIES



## 5 NICOTINE STRENGTHS



NO TOBACCO LEAF



Nicotine pouches

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

# 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

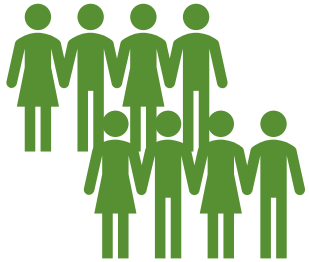
- Risk Perceptions (absolute and relative)
- Impact of Product on Users
- Impact on Non-Users
- Overall Impact on the Population
- Environmental Assessment

# Perception & Behavioral Intentions Study Among Users and Nonusers



POPULATION HARM REDUCTION

## Participants



**Tobacco Users**  
ASPQ, ASNPQ, DU, ST Users

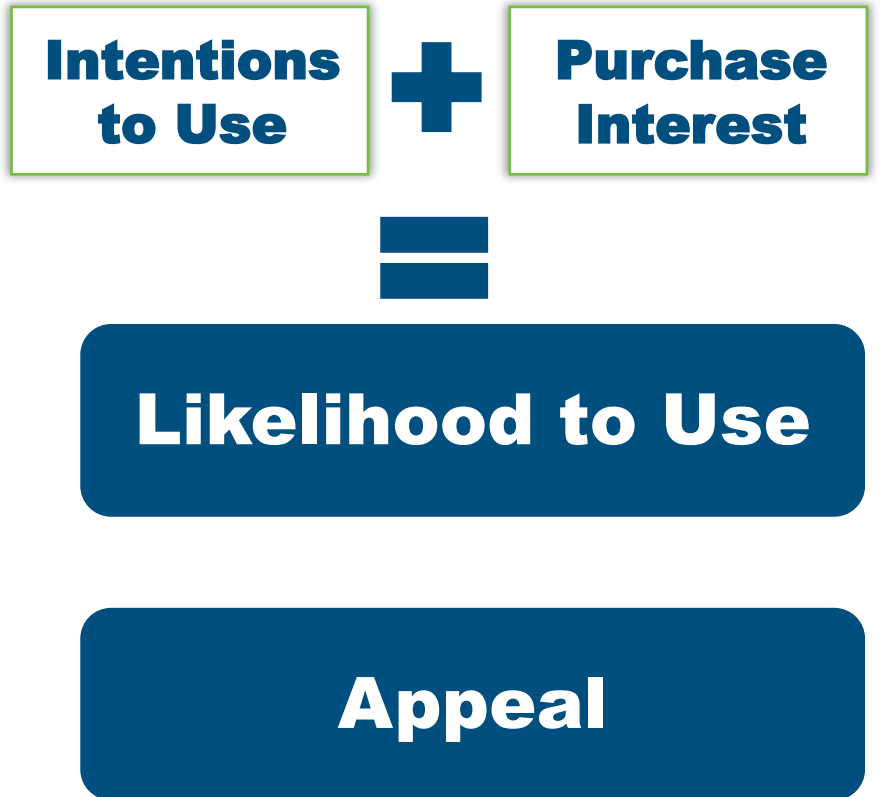


**Tobacco Nonusers**  
Former Users, Never Users

## Exposure to Promotional Materials



## Measures

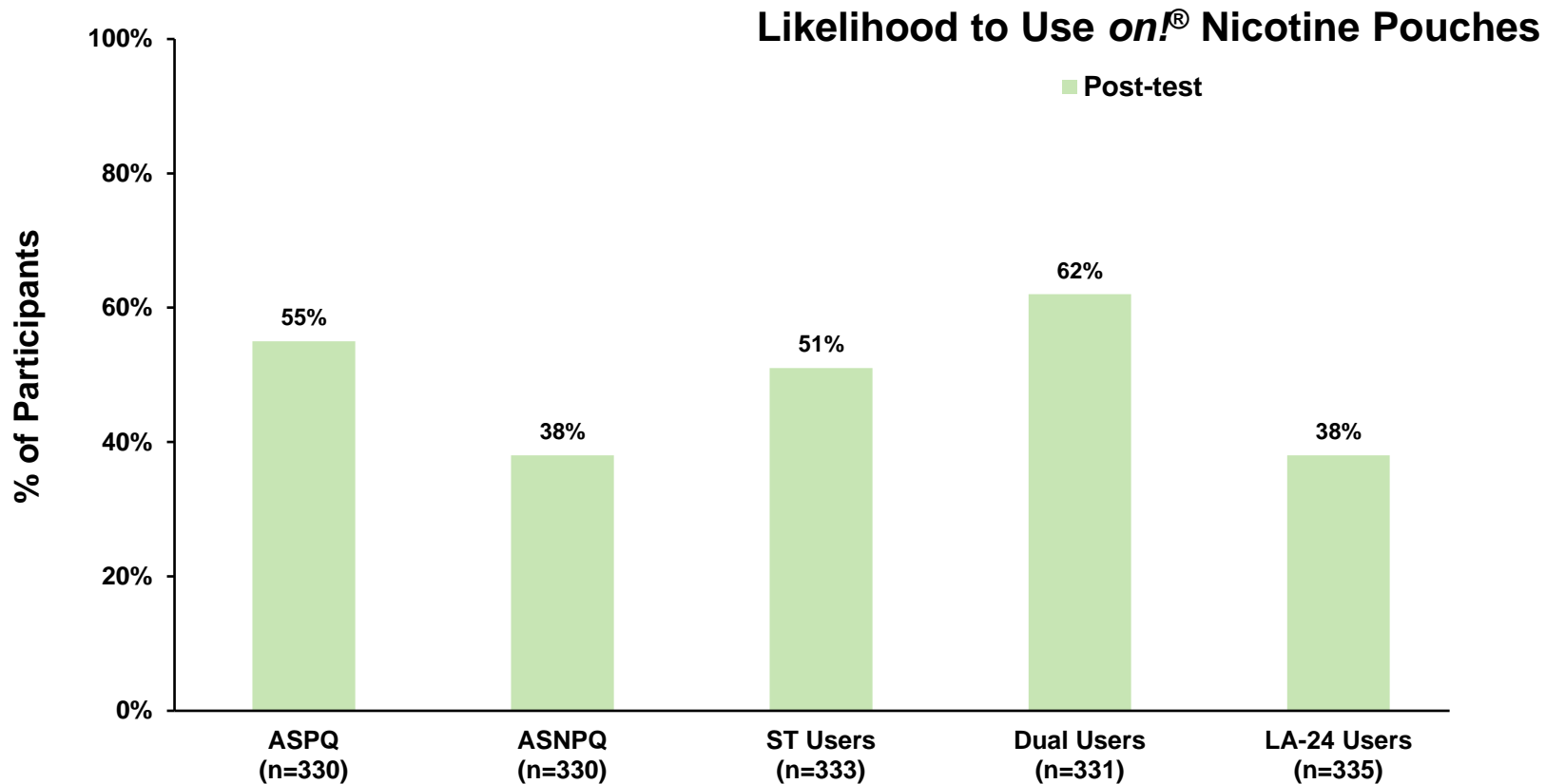


ASPQ – Adult Smokers Planning to Quit; ASNPQ – Adult Smokers Not Planning to Quit; DU – Dual Users; ST Users – Smokeless Tobacco Users

# Moderate to Large Proportion of Adults Who Use Tobacco Classified as Likely to Use *on!*<sup>®</sup>



POPULATION HARM REDUCTION



Results shown in the chart are from participants assigned to Reduced Exposure condition. Similar results were observed among tobacco user groups assigned to Full Exposure Condition. Likelihood to use the *on!*<sup>®</sup> product was based on an intention composite score >3.5 and answered Yes to the purchase intent question.

ASPQ=adult smokers planning to quit; ASN PQ=adult smokers not planning to quit; LA=Legal age to purchase tobacco; ST=smokeless tobacco.

Source: *Perception and Behavioral Intentions Study Report*

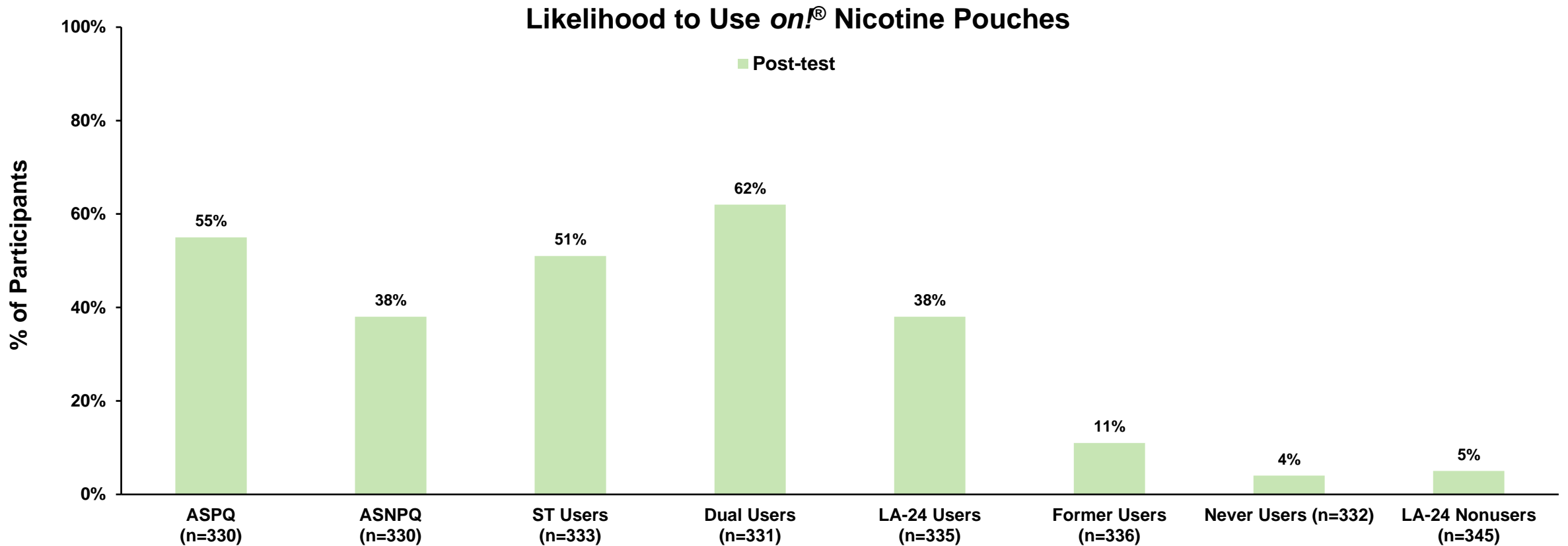


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# Small Proportion of Nonusers Classified as Likely to Use *on!*<sup>®</sup>



POPULATION HARM REDUCTION



Results shown in the chart are from participants assigned to Reduced Exposure condition. Similar results were observed among tobacco user groups assigned to Full Exposure Condition. Likelihood to use the *on!*<sup>®</sup> product was based on an intention composite score >3.5 and answered Yes to the purchase intent question.

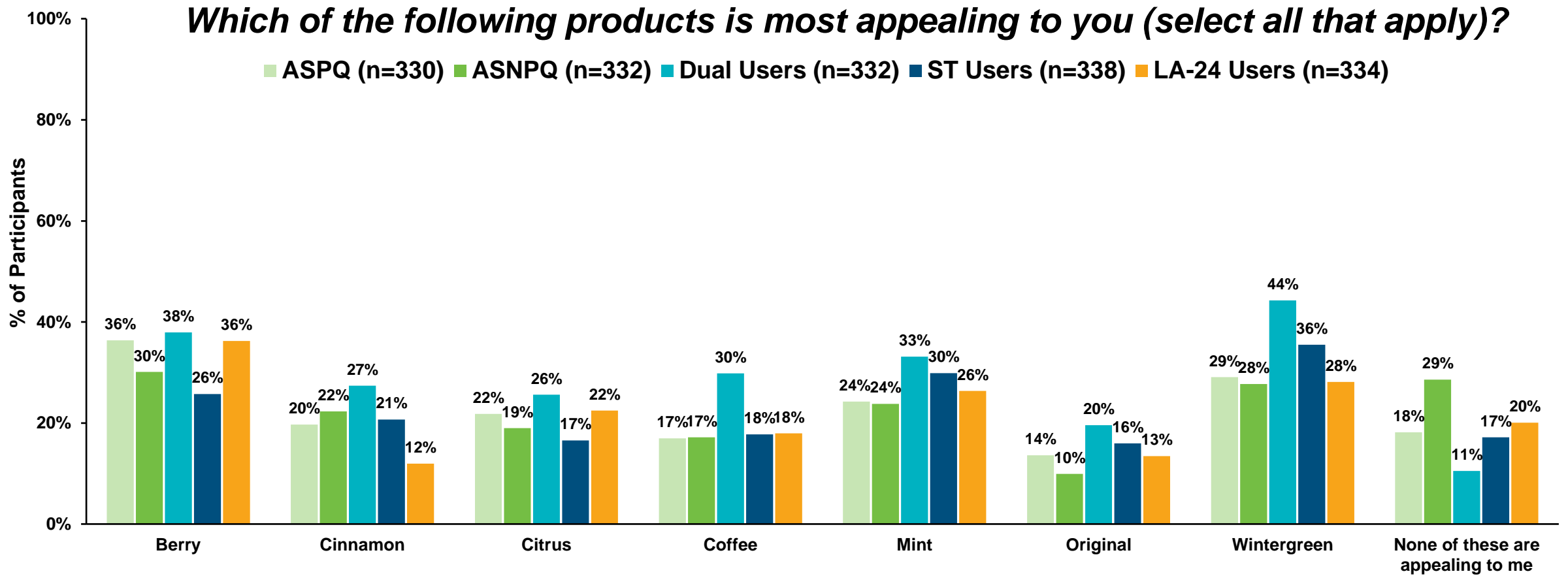
ASPQ=adult smokers planning to quit; ASNPQ=adult smokers not planning to quit; LA=Legal age to purchase tobacco; ST=smokeless tobacco.

Source: *Perception and Behavioral Intentions Study Report*

# Majority of Adults Who Use Tobacco Found at Least One Flavor Appealing



POPULATION HARM REDUCTION



Results shown in the chart are from participants assigned to Full Exposure condition. Similar results were observed among tobacco user groups assigned to Reduced Exposure Condition. ASPQ – Adult Smokers Planning to Quit; ASNPQ – Adult Smokers Not Planning to Quit; DU – Dual Users; ST Users – Smokeless Tobacco Users

Source: *Perception and Behavioral Intentions Study Report*



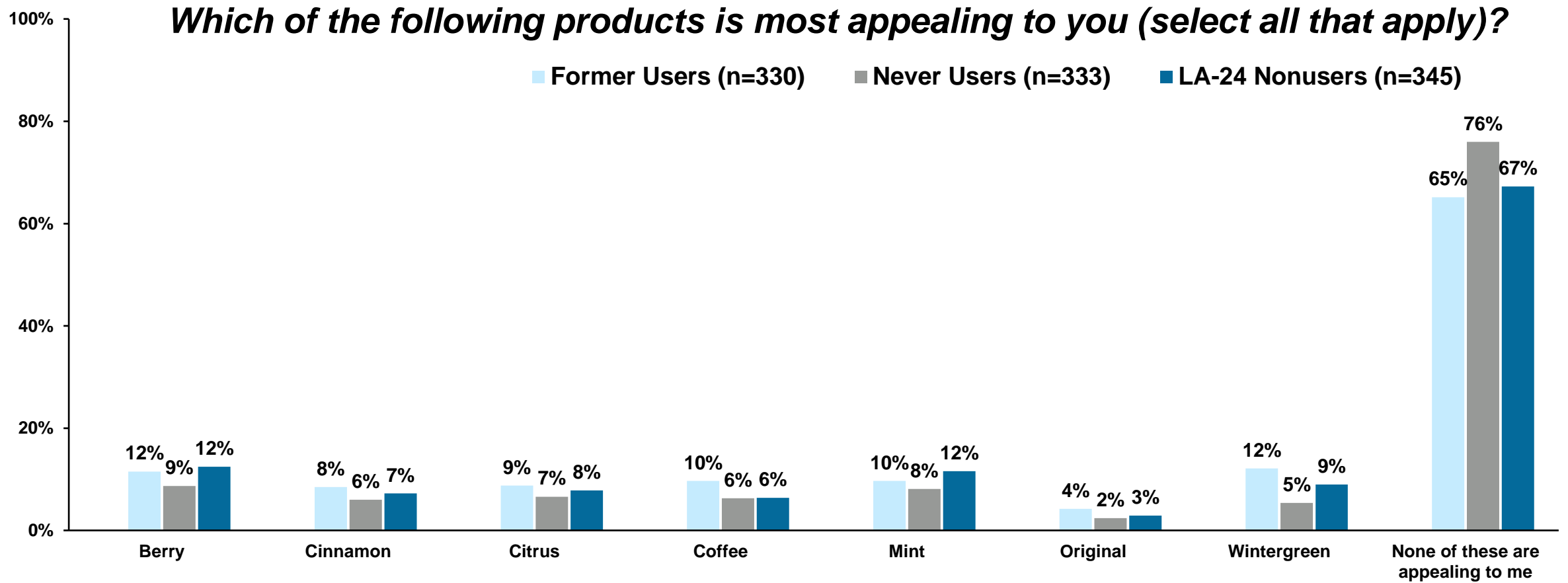
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# Most Nonusers Indicated None of the Products Were Appealing



POPULATION HARM REDUCTION



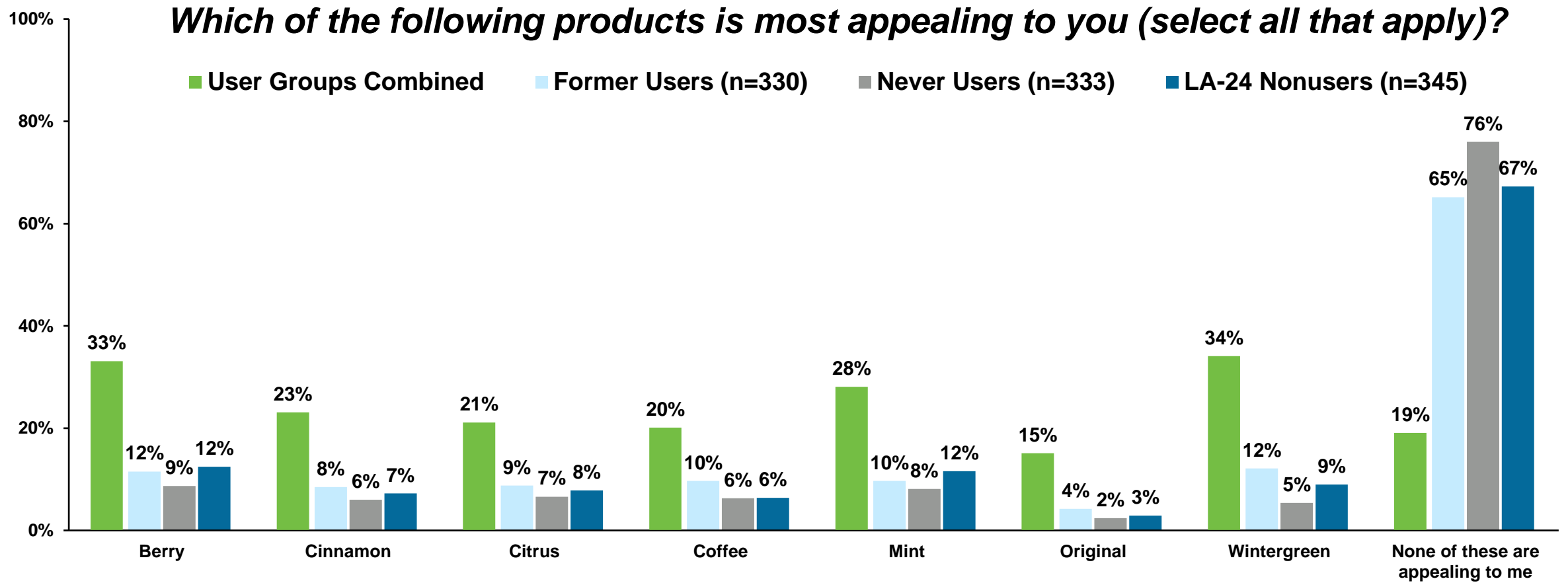
Results shown in the chart are from participants assigned to Full Exposure condition. Similar results were observed among tobacco user groups assigned to Reduced Exposure Condition.  
Source: *Perception and Behavioral Intentions Study Report*



# Compared to Tobacco Users, More Nonusers Indicated None of the Products Were Appealing



POPULATION HARM REDUCTION



Results shown in the chart are from participants assigned to Full Exposure condition. Similar results were observed among tobacco user groups assigned to Reduced Exposure Condition.  
 Source: *Perception and Behavioral Intentions Study Report*



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### Case Study: *on!*<sup>®</sup> Nicotine Pouches

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## Underage Use of Smoke-free Products



# Actual Use Study of *on!*<sup>®</sup> Nicotine Pouches



POPULATION HARM REDUCTION

## Participants

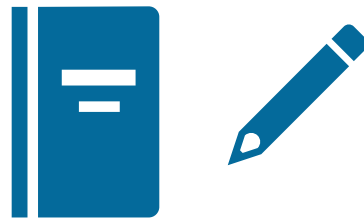


Tobacco Users  
Interested in Using *on!*<sup>®</sup>  
Nicotine Pouches and  
Not Planning to Quit  
AS, DU, ST Users

## Free Selection of Product



## Daily and Weekly Diaries



## Outcomes

Frequency and Amount  
of Use by Variety

Time in Mouth

Likeability

AS – Adults who smoke; DU – Adults who use cigarettes and smokeless tobacco products;  
ST Users – Adults who use smokeless tobacco



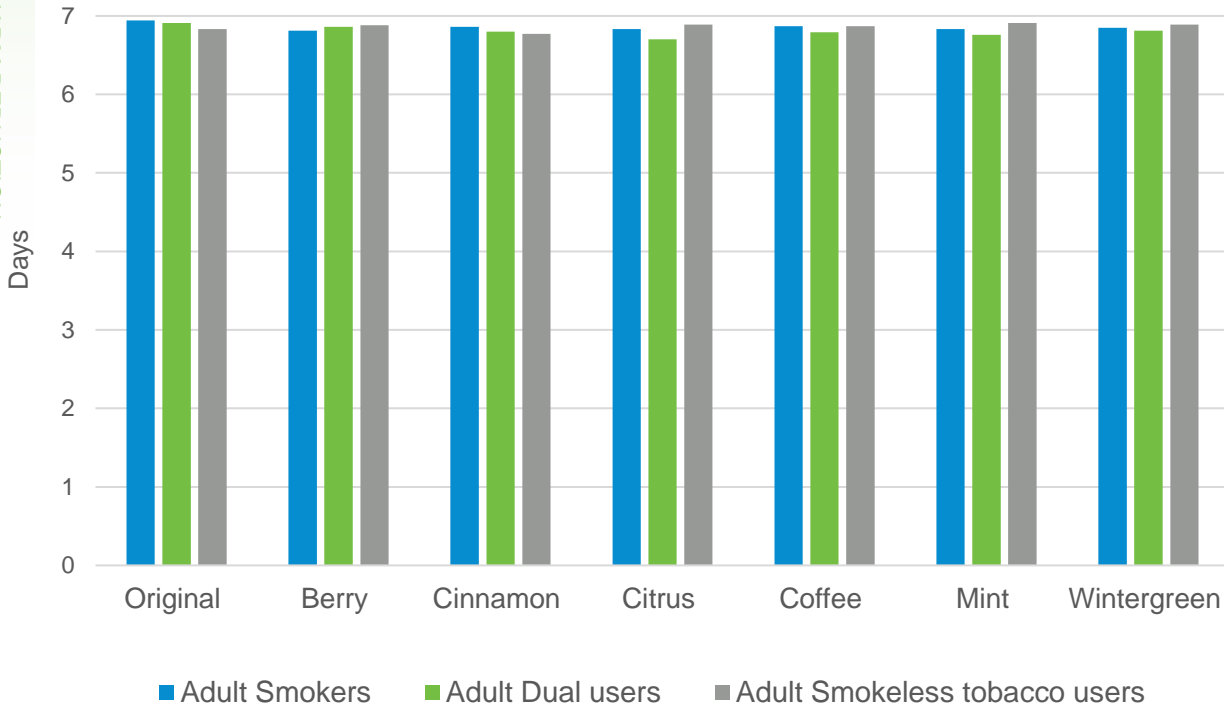
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# Use Behaviors Were Consistent Across Flavors



POPULATION HARM REDUCTION

Mean number of days of *on!*® nicotine pouch use among those who used the flavor variety at week 6



Source: AUS Study Report



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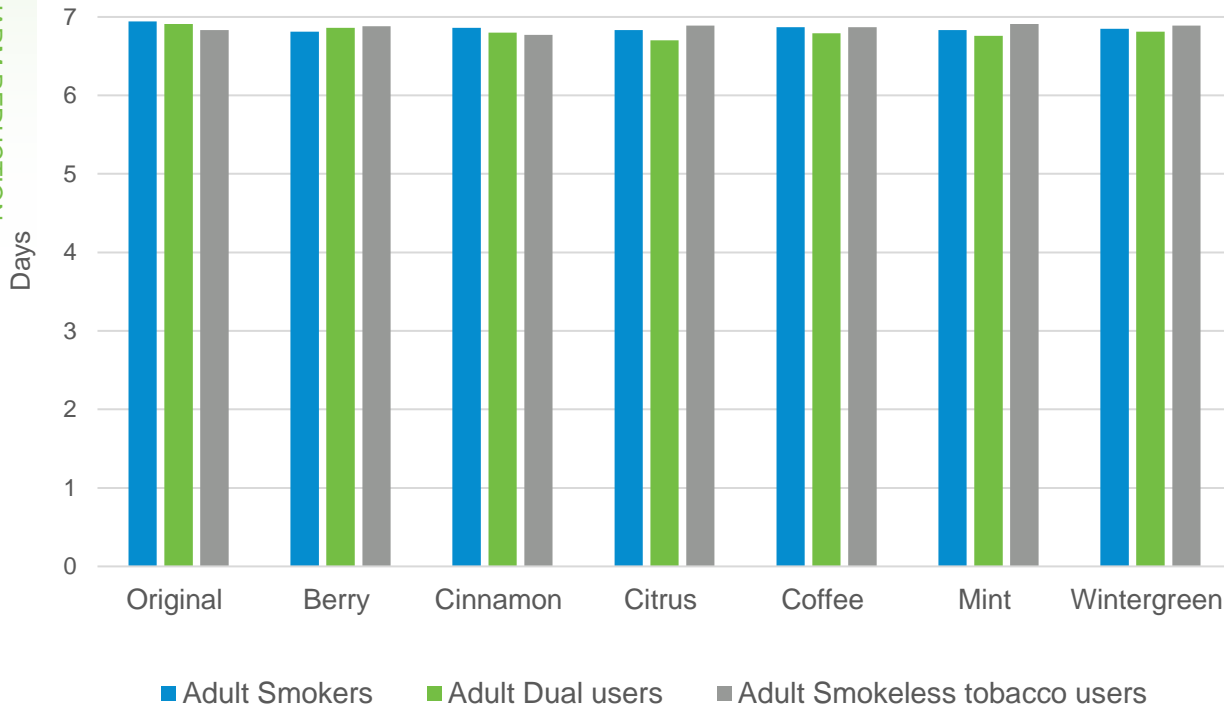
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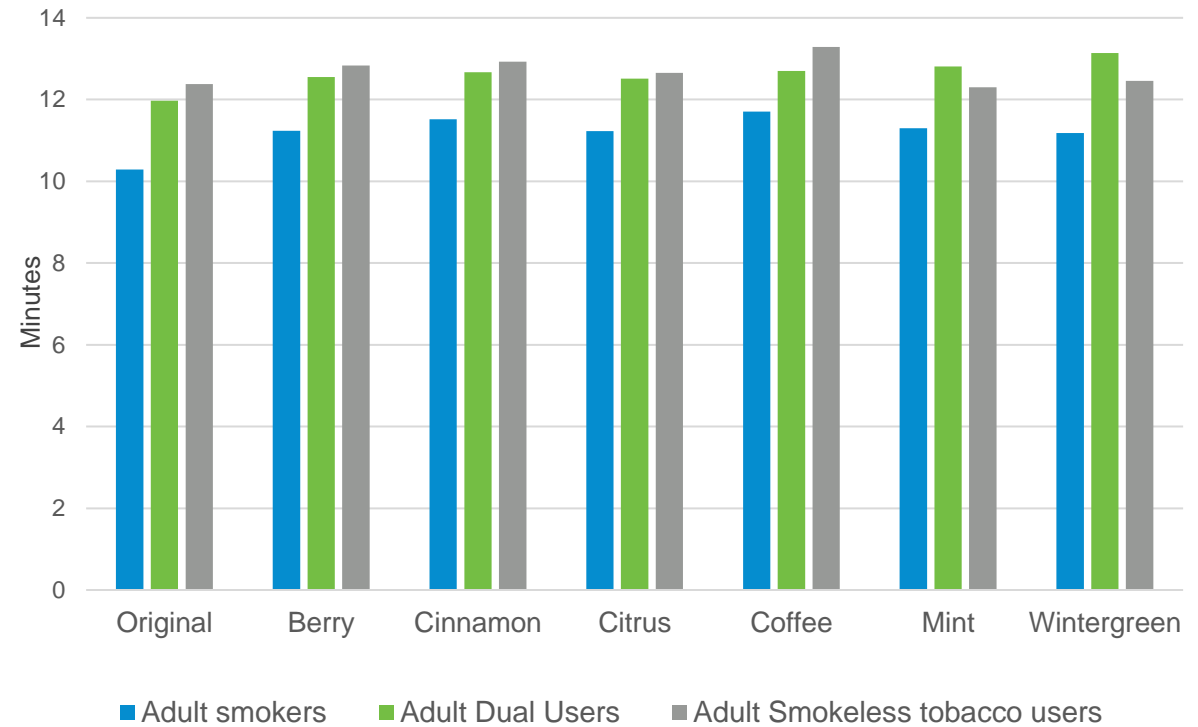


POPULATION HARM REDUCTION

Mean number of days of *on!*® nicotine pouch use among those who used the flavor variety at week 6



Mean length of time in mouth per use occasion



Source: AUS Study Report



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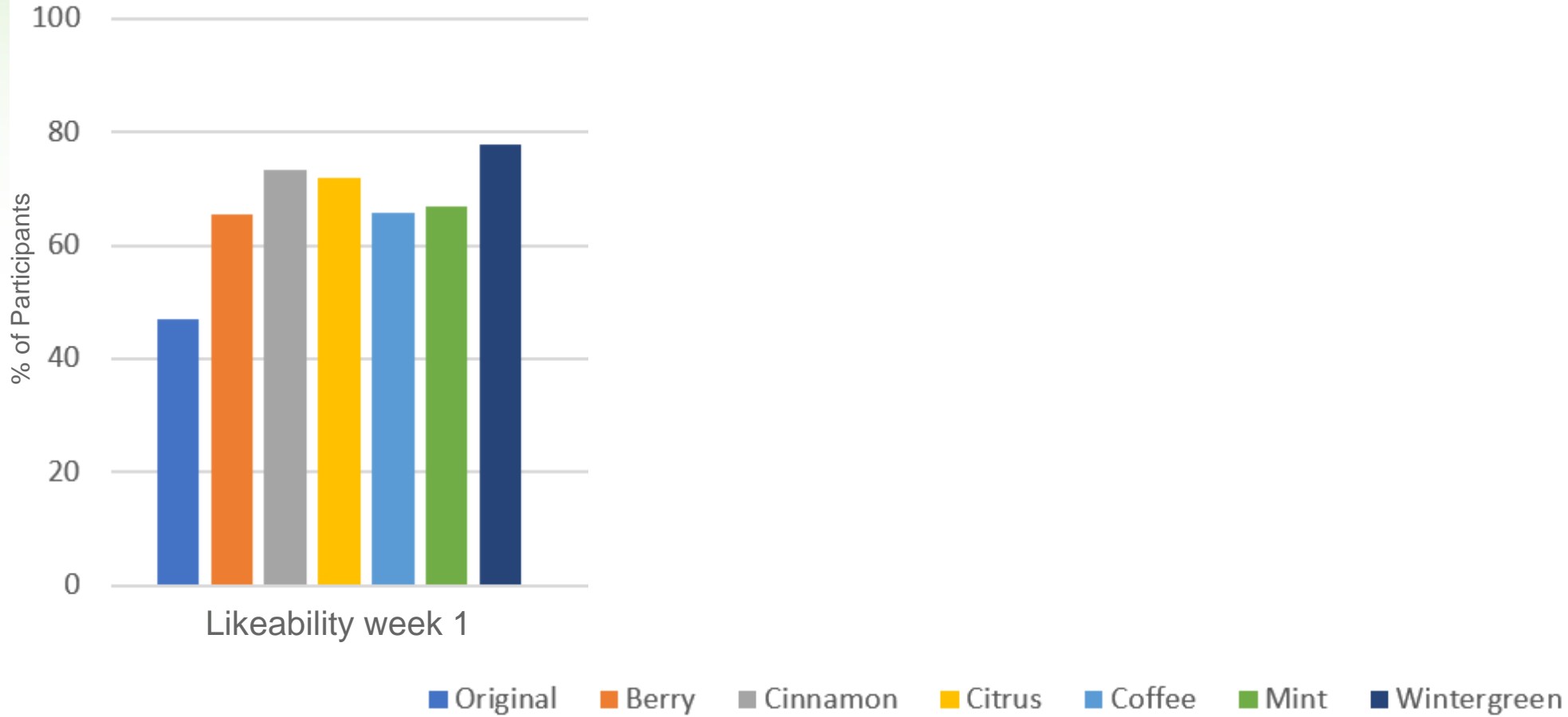
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# Greater Interest and Use of Flavored Varieties Compared to the Original Variety of *on!*<sup>®</sup> Nicotine Pouches



POPULATION HARM REDUCTION

## Product Likeability, Prevalence, and Purchase Interest by Variety Among Adults Who Smoke



Source: AUS Study Report



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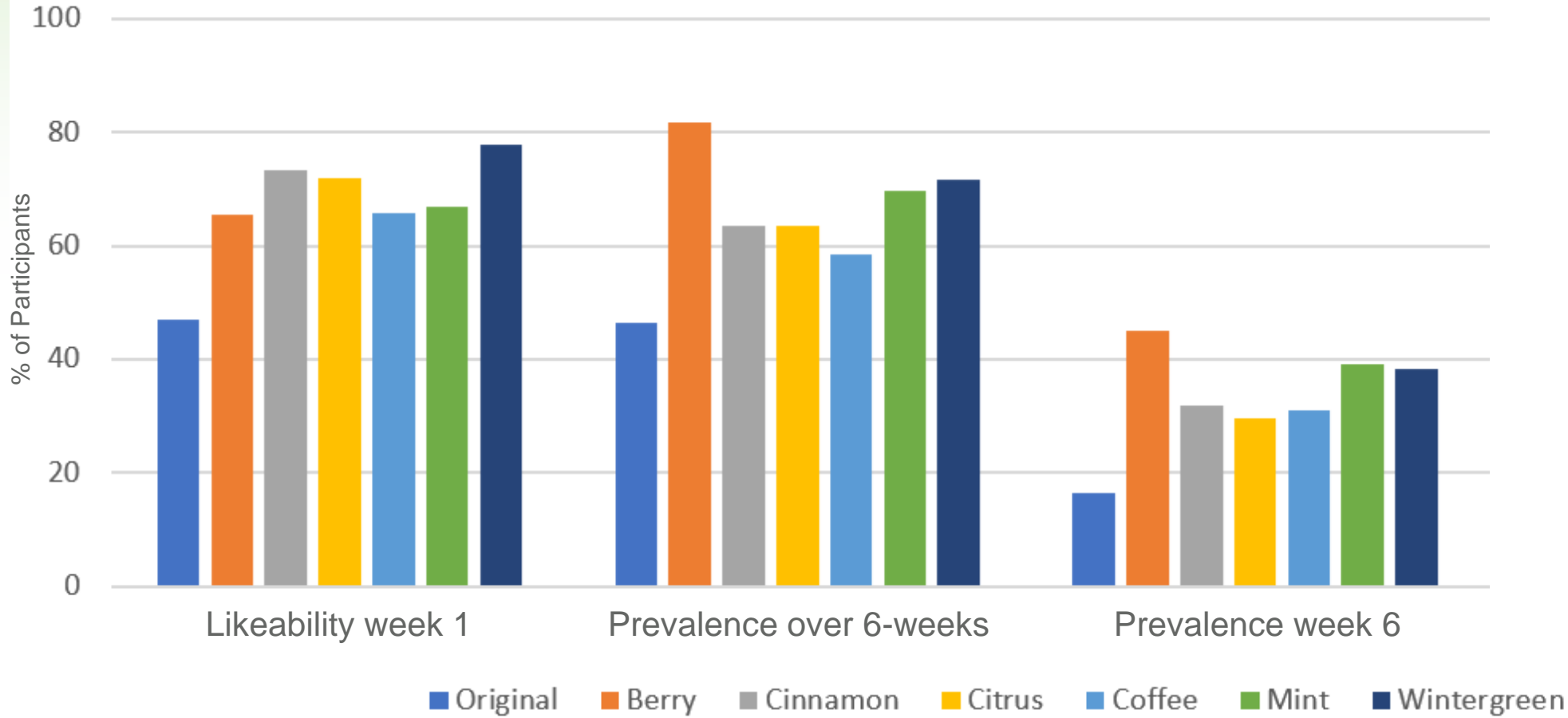
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# Greater Interest and Use of Flavored Varieties Compared to the Original Variety of *on!*<sup>®</sup> Nicotine Pouches



POPULATION HARM REDUCTION

Product Likeability, Prevalence, and Purchase Interest by Variety Among Adults Who Smoke



Source: AUS Study Report



Altria

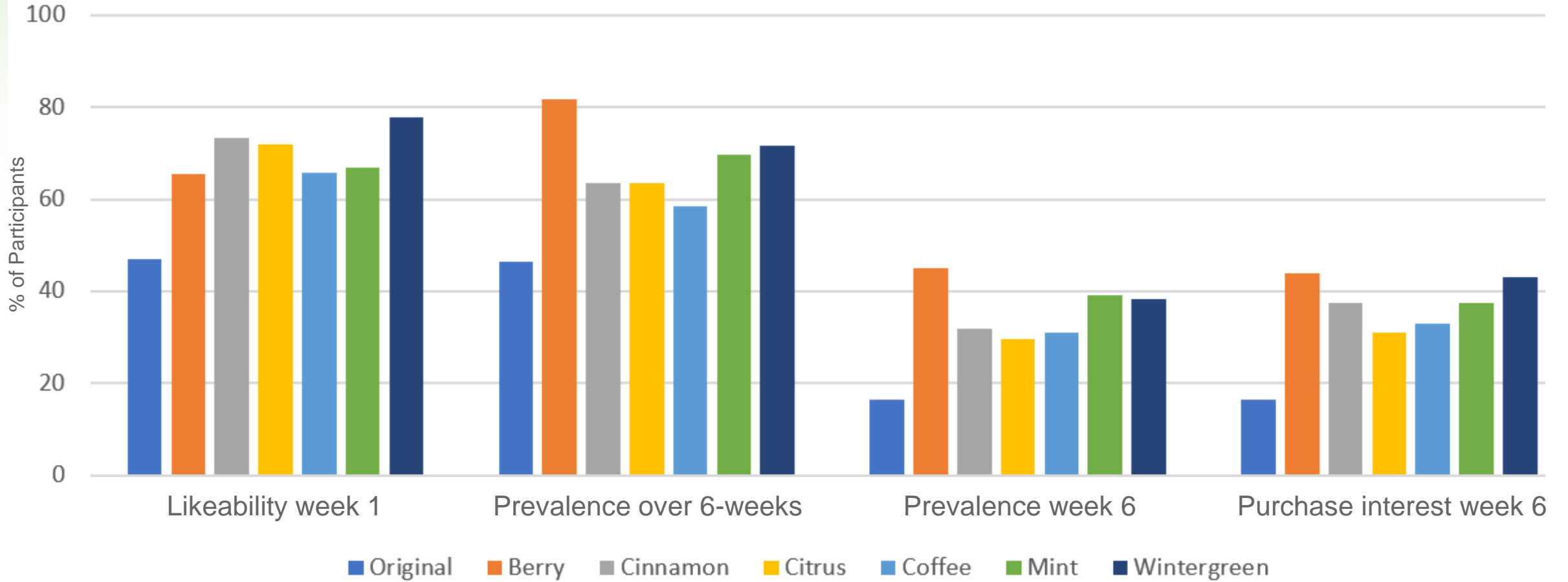
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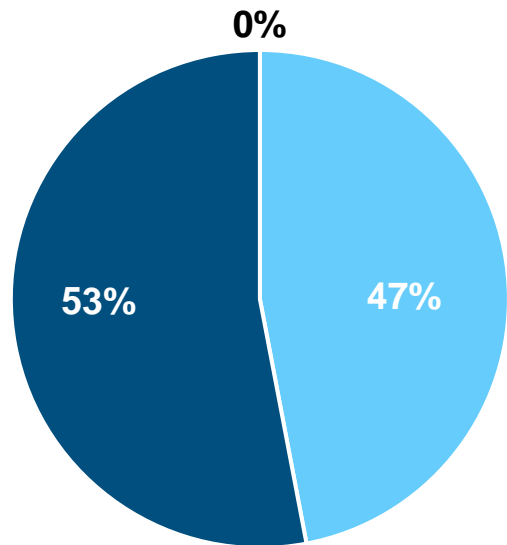


# Overall Preference for Flavored Varieties



POPULATION HARM REDUCTION

Varieties Used Over 6-Weeks



- Used Original Exclusively
- Used Both Original and Flavored
- Used Flavored Varieties Exclusively

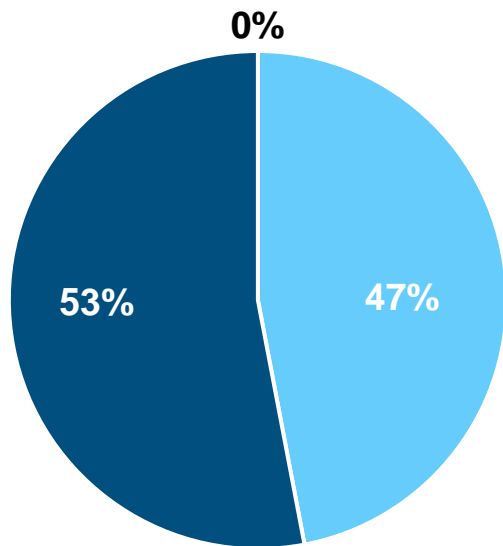
Source: AUS Study, Additional ALCS analysis

# Overall Preference for Flavored Varieties



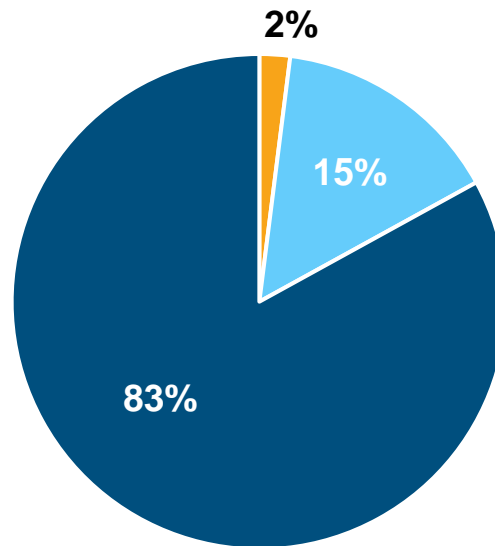
POPULATION HARM REDUCTION

### Varieties Used Over 6-Weeks



- Used Original Exclusively
- Used Both Original and Flavored
- Used Flavored Varieties Exclusively

### Varieties Used During Week 6



- Used Original Exclusively
- Used Both Original and Flavored
- Used Flavored Varieties Exclusively

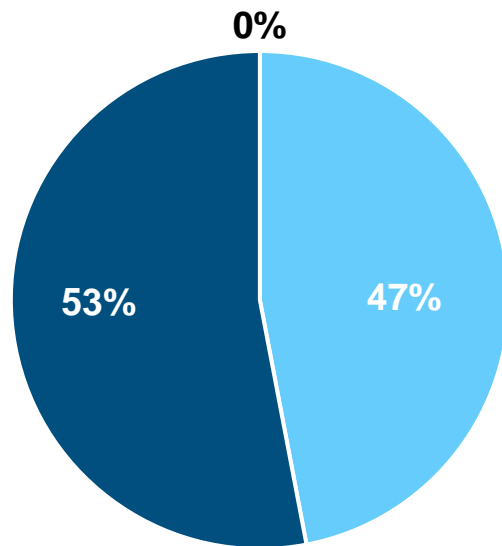
Source: AUS Study, Additional ALCS analysis

# Overall Preference for Flavored Varieties



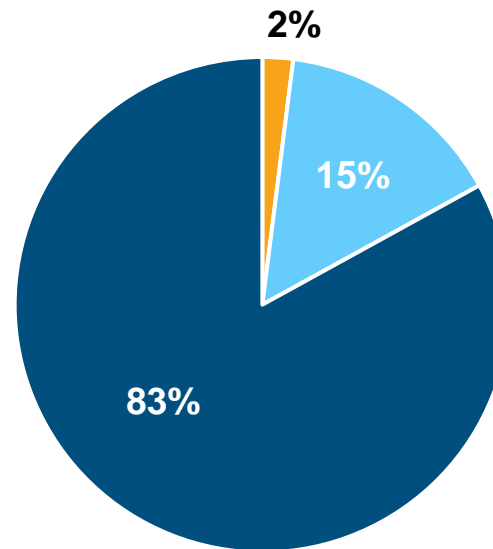
POPULATION HARM REDUCTION

### Varieties Used Over 6-Weeks



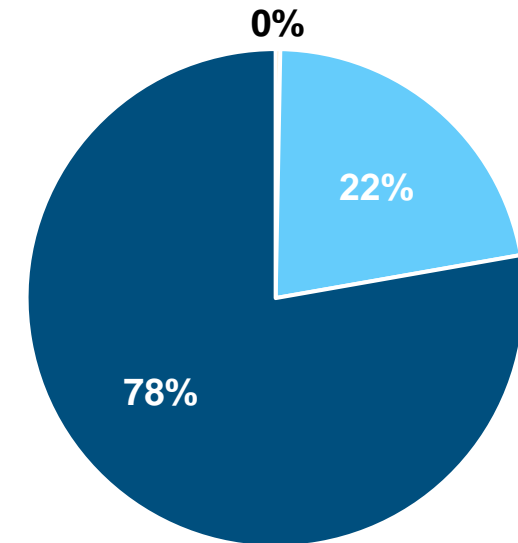
- Used Original Exclusively
- Used Both Original and Flavored
- Used Flavored Varieties Exclusively

### Varieties Used During Week 6



- Used Original Exclusively
- Used Both Original and Flavored
- Used Flavored Varieties Exclusively

### Purchase Interest Week 6



- Original Only
- Both Original and Flavored
- Flavored Only

Source: AUS Study, Additional ALCS analysis



## Background: Tobacco Use and Flavors

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### Case Study: *on!*<sup>®</sup> Nicotine Pouches

Intentions &  
Appeal

Use &  
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Behavioral  
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## Underage Use of Smoke-free Products



# Actual Use Study of *on!*<sup>®</sup> Nicotine Pouches



POPULATION HARM REDUCTION

## Participants



Tobacco Users  
Interested in Using *on!*<sup>®</sup>  
Nicotine Pouches and  
Not Planning to Quit  
AS, DU, ST Users

## Free Selection of Product

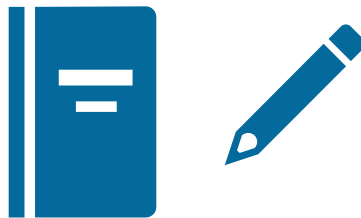


## Outcomes

**Complete Switching**

**Reduction in Cigarettes  
or Smokeless Tobacco  
Use**

## Daily and Weekly Diaries



AS – Adults who smoke; DU – Adults who use cigarettes and smokeless tobacco products;  
ST Users – Adults who use smokeless tobacco

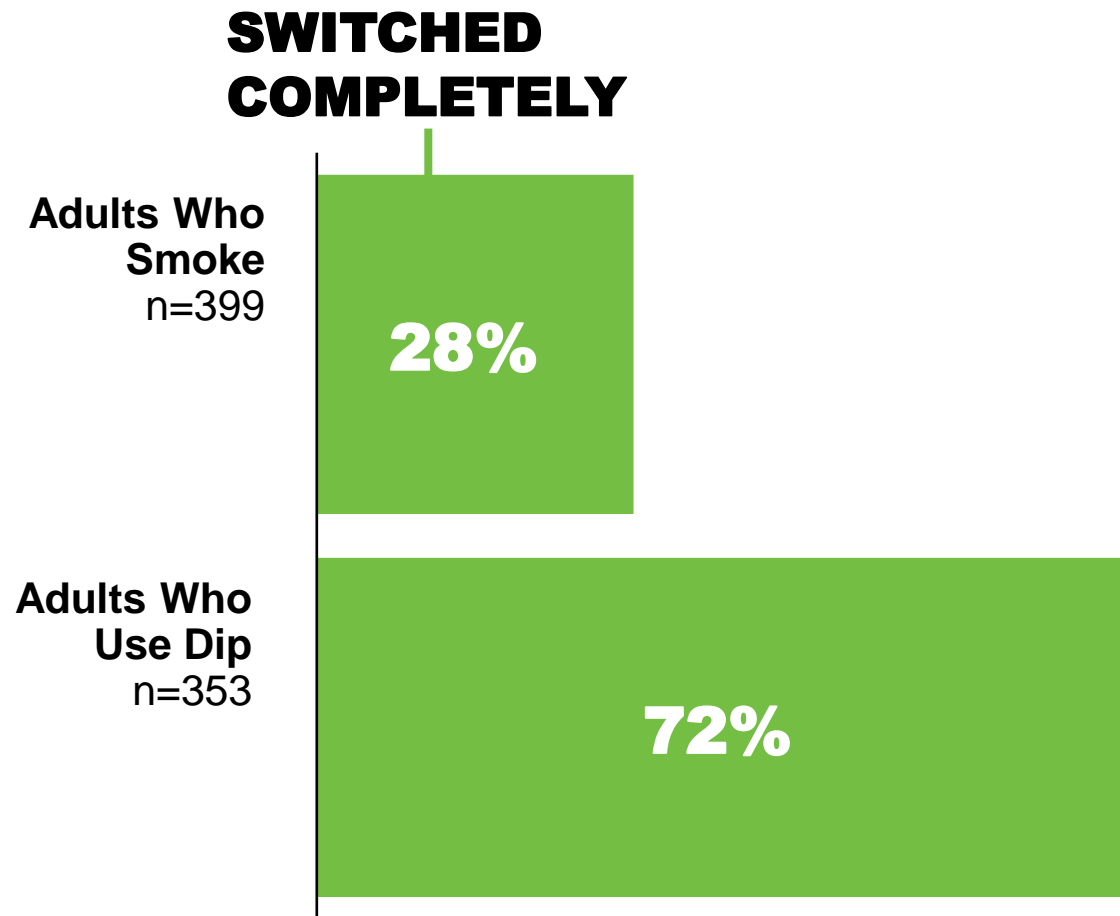


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# Large Proportions of Adult Tobacco Users Switched or Reduced Traditional Tobacco Use



POPULATION HARM REDUCTION



Source: AUS Study Report; Switching completely assessed at end of study



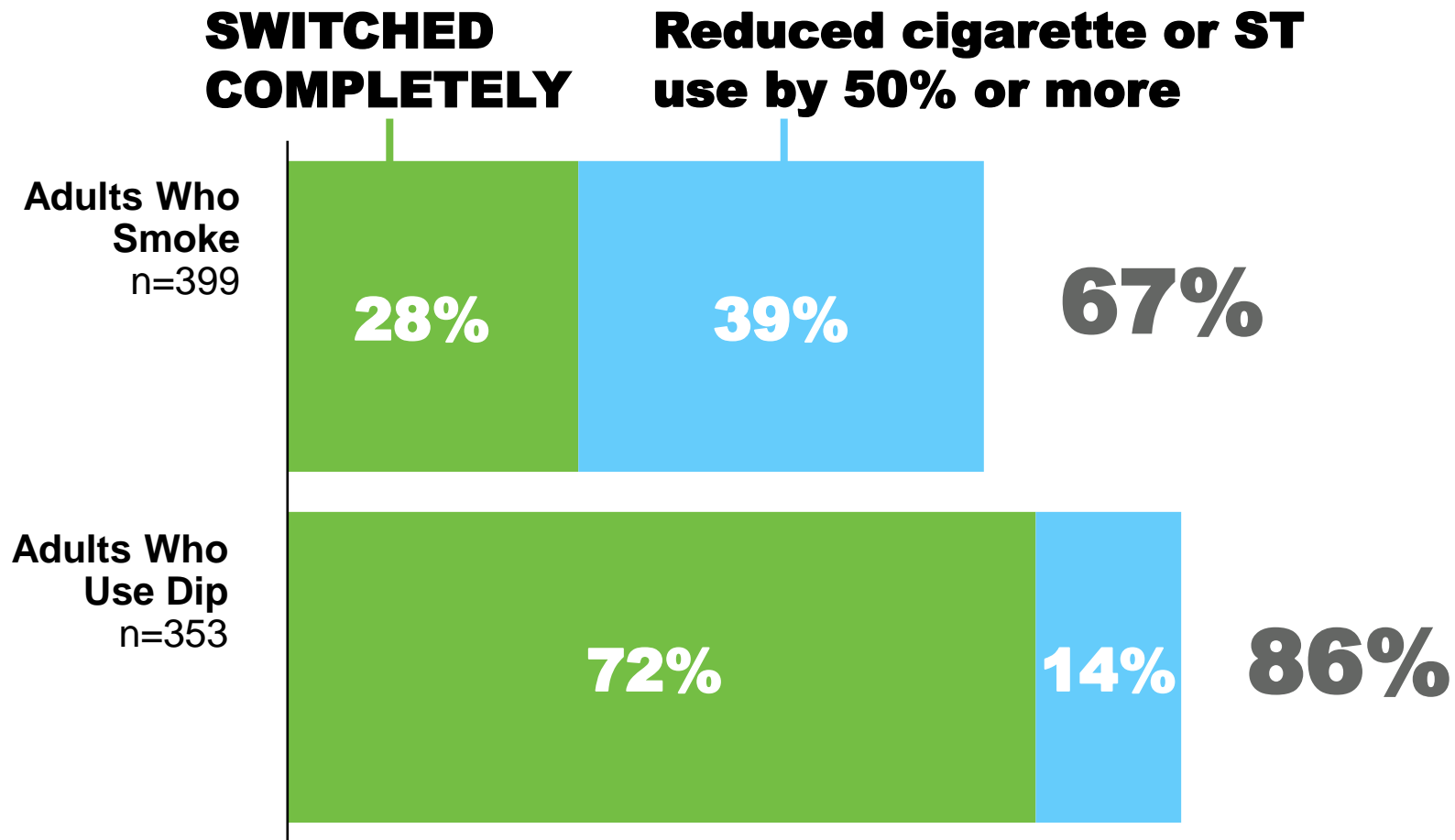
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# Large Proportions of Adult Tobacco Users Switched or Reduced Traditional Tobacco Use



POPULATION HARM REDUCTION

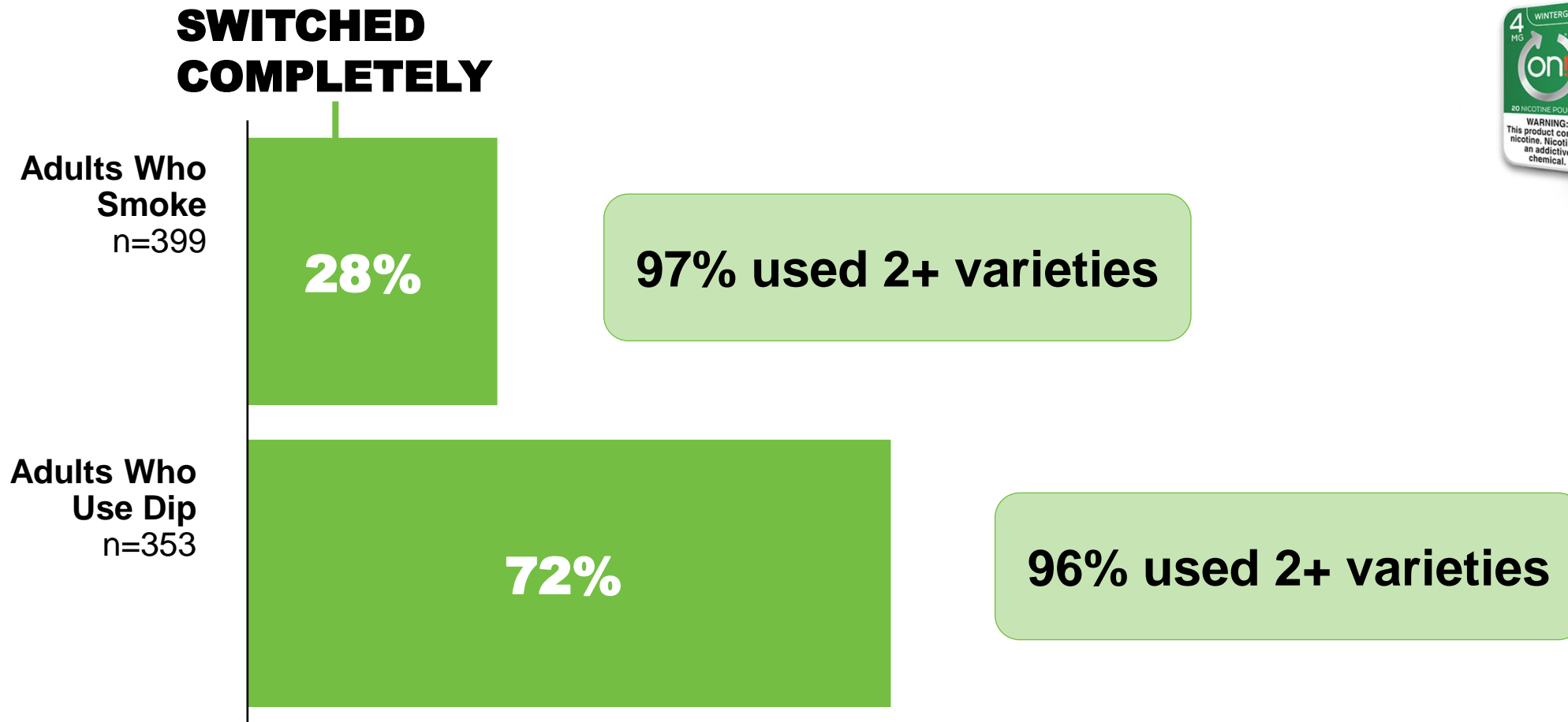


Source: AUS Study Report and additional ALCS analysis  
ST: Smokeless Tobacco.

# Large Proportions of Adult Tobacco Users Switched or Reduced Traditional Tobacco Use



POPULATION HARM REDUCTION



Source: AUS Study Report



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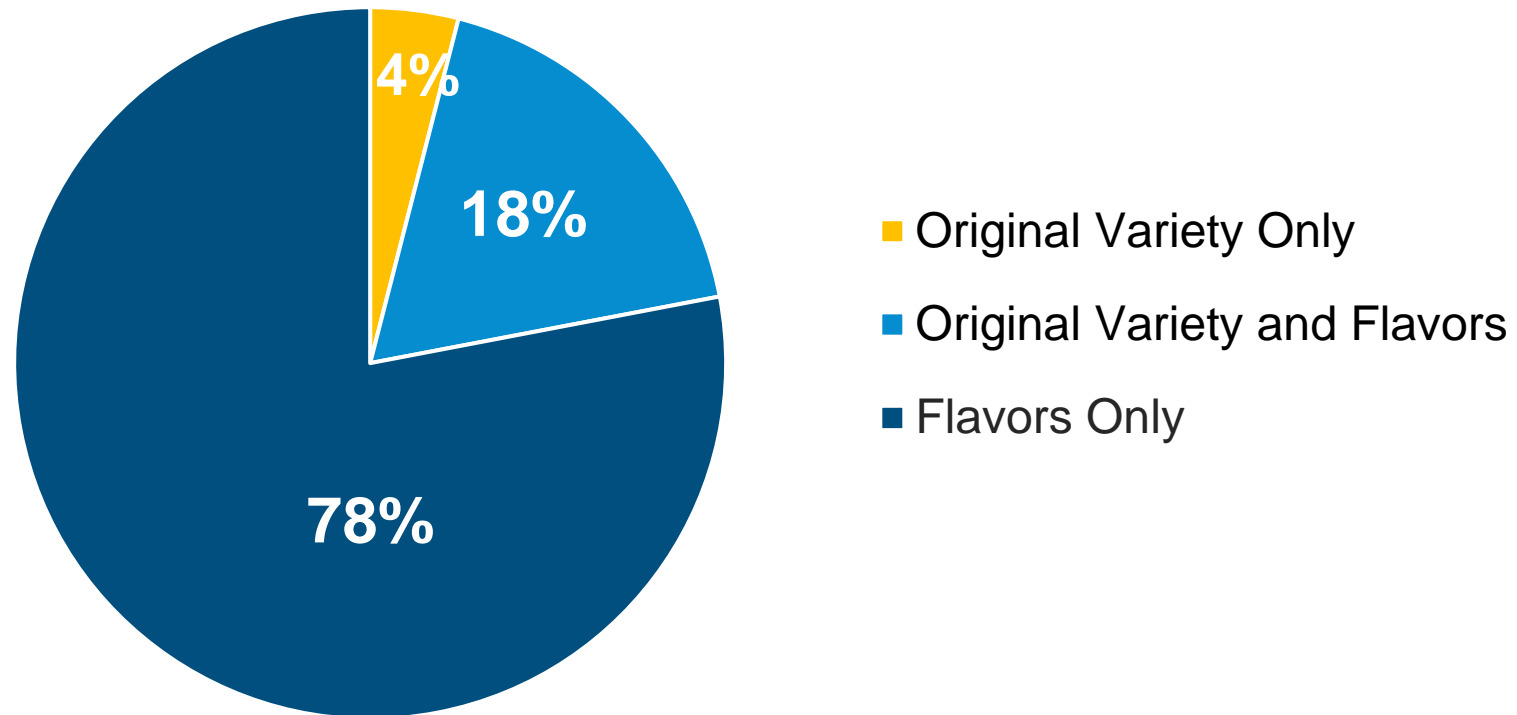


# Most AS Used Flavored *on!*<sup>®</sup> Nicotine Pouches when Switching



POPULATION HARM REDUCTION

Use of the Original Variety and All Other Combination of Varieties by Adult Smokers Who Switched to *on!*<sup>®</sup> Nicotine Pouches in Week 6



Source: AUS Study, Additional ALCS analysis

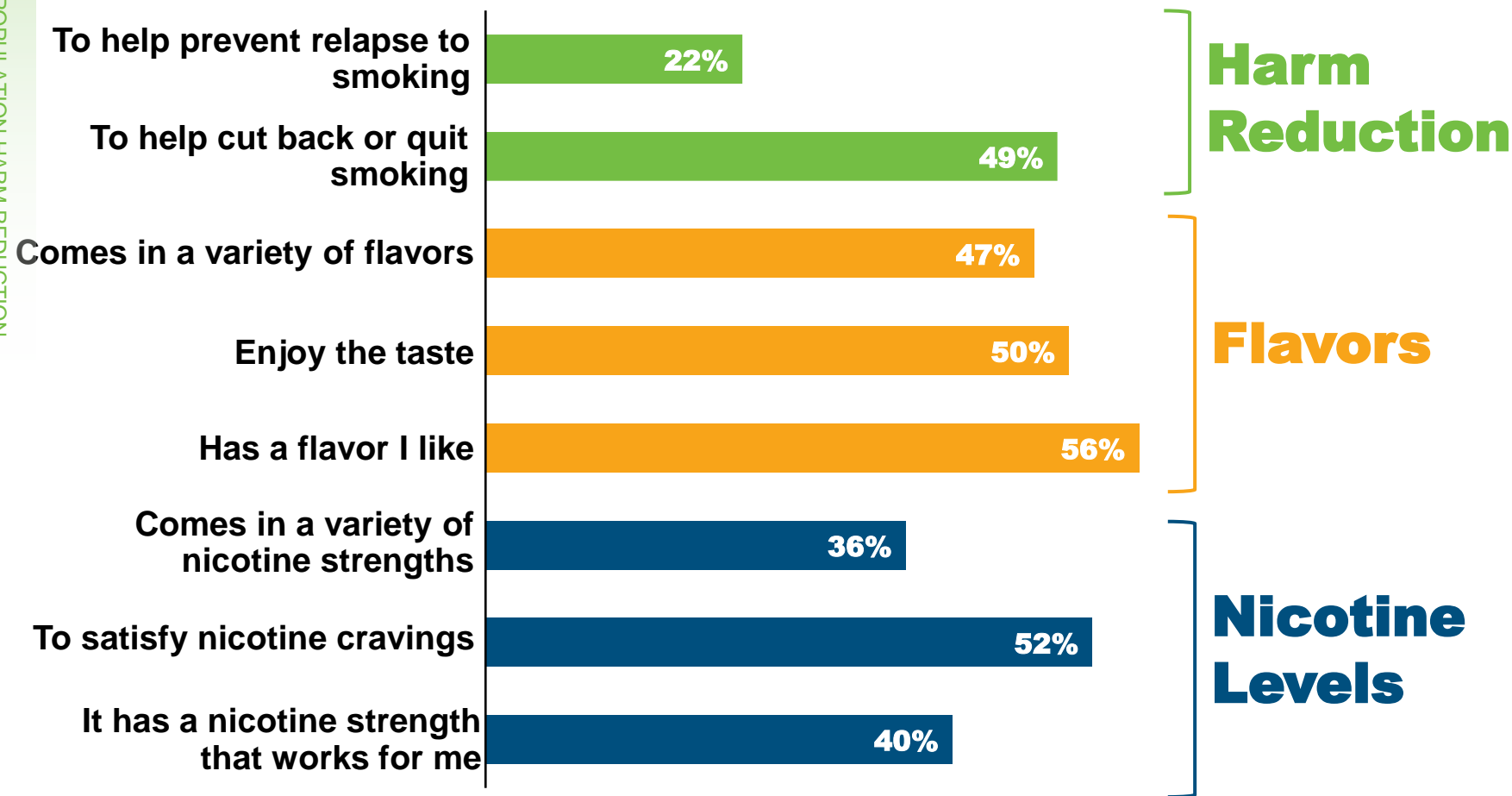


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# Reasons for Future Use of *on!*<sup>®</sup> Nicotine Pouches Among Adults who Smoke Likely to Use *on!*<sup>®</sup> Nicotine Pouches

POPULATION HARM REDUCTION



Percentage of adults who smoke who endorsed each reason why they would use *on!*<sup>®</sup> in the future





## Background: Tobacco Use and Flavors

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### Case Study: *on!*<sup>®</sup> Nicotine Pouches

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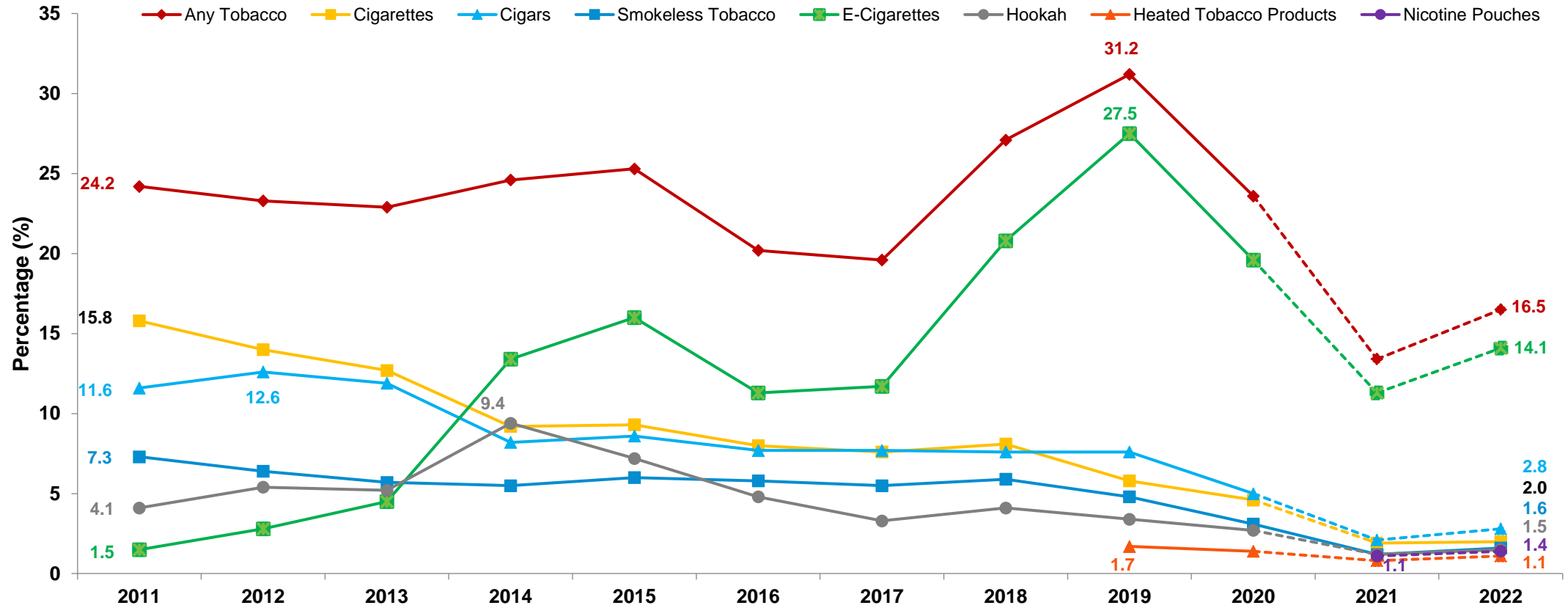
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## Underage Use of Smoke-free Products



# Current Tobacco Product Use Among High School Students

Current Tobacco Product Use Among High School Students, *National Youth Tobacco Survey, 2011-2022*

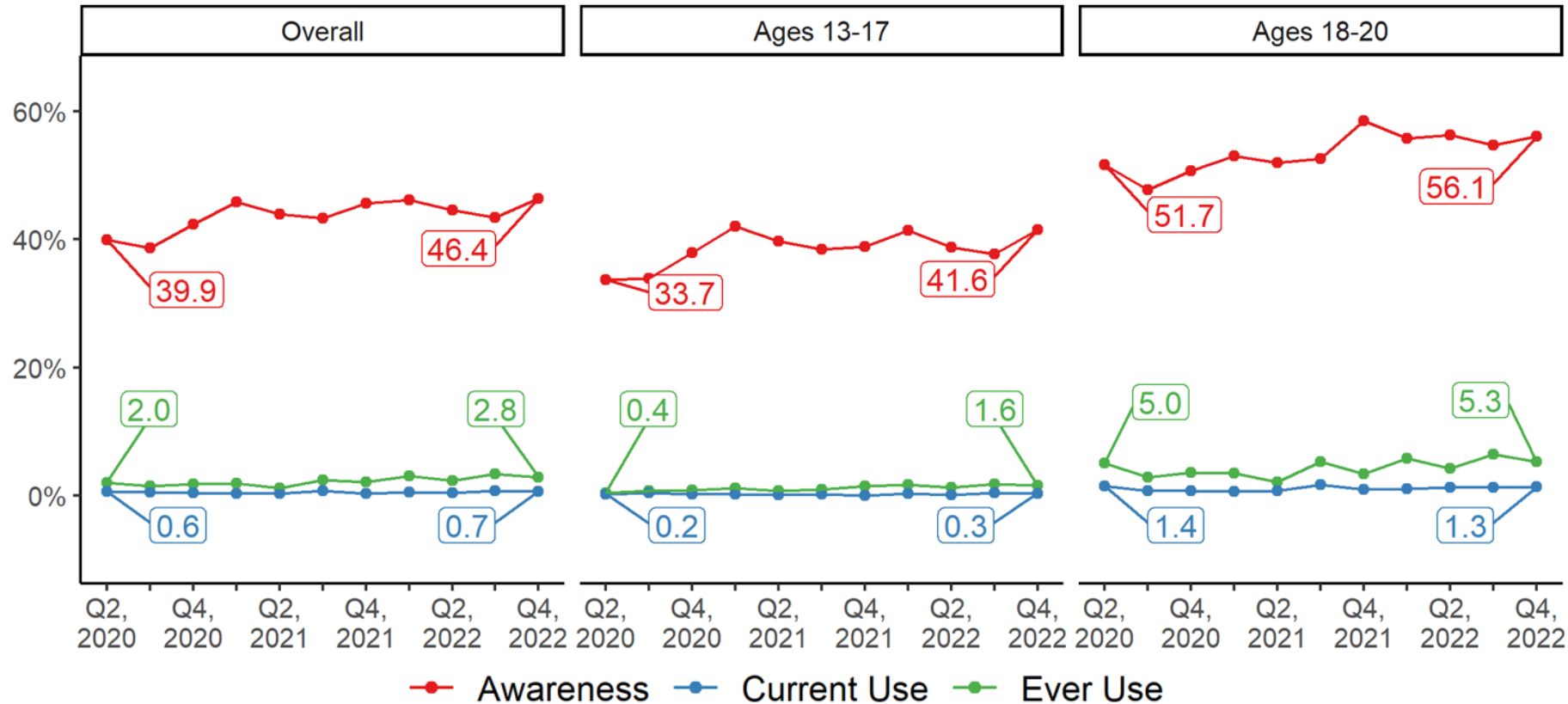


Sources: [Tobacco Product Use Among Middle and High School Students — United States, 2011–2018](#); [Tobacco Product Use and Associated Factors Among Middle and High School Students — United States, 2019](#); [Tobacco Product Use Among Middle and High School Students — United States, 2020](#), and [Tobacco Product Use and Associated Factors Among Middle and High School Students — United States, 2021](#); [Tobacco Product Use Among Middle and High School Students — United States, 2022](#)  
 Source for 2019 data on Heated Tobacco Products: [Heated tobacco product use and associated factors among U.S. youth, 2019](#)

Note: Any tobacco use is past 30-day use of cigarettes, cigars, smokeless tobacco, electronic cigarettes, hookahs, pipe tobacco, and/or bidis, in addition to heated tobacco products (2020-2022) and nicotine pouches (2021-2022) on ≥ 1 day in the past 30 days.  
 Note: in 2014 and 2015, modifications were made to the e-cigarette measure to enhance its accuracy, which may limit the comparability of these estimates to those collected in previous years. In 2019, modifications were made to the survey, as well as the e-cigarette measure through inclusion of a brand example (JUUL); authors caution against comparisons to prior years. For smokeless tobacco, 2015 and prior years data are not comparable due to methodological changes into 2015. In 2015 smokeless tobacco includes chewing tobacco/snuff/dip, snus, and dissolvable tobacco because of limited sample sizes. Prior to 2015, smokeless tobacco included only chewing tobacco/snuff/dip. Due to changes in methodologies, including differences in survey administration and data collections procedures, the ability to compare estimates from 2022 to previous years is limited. Dashed lines from 2020-2022 represent these differences.

# Moderate Awareness, Low Trial and Use of Nicotine Pouches

Awareness and Use of Nicotine Pouches over Time  
Data from UTUS 2020 - 2022 (n=16,524)



Awareness: % participants who had seen or heard of nicotine pouches before  
 Ever use: % participants who ever used nicotine pouches even once  
 Current use: % participants who have used nicotine pouches in the past 30 days

Source: Underage Tobacco Use Survey (2022)

Scan for more info about Altria's Underage Tobacco Use Survey



# Summary

- Flavors play an important role in tobacco harm reduction
- Adults who use tobacco prefer flavored *on!*<sup>®</sup> nicotine pouches over the Original variety
  - Adults who use tobacco perceived the flavored *on!*<sup>®</sup> nicotine pouches as more appealing than the Original variety
  - Adults who use tobacco preferred to use the flavored *on!*<sup>®</sup> nicotine pouches over the Original variety
  - Flavors play a role as adults who use tobacco switch to *on!*<sup>®</sup> nicotine pouches and stop smoking cigarettes and/or using smokeless tobacco
- While our data show that flavors do not play a role in *how* adults who use tobacco use *on!*<sup>®</sup> nicotine pouches, flavors are important to *whether* they will select, use and switch to them
- To preserve the harm reduction opportunity for adults who use tobacco, we must monitor and help prevent underage use of potentially reduced harm products





# Acknowledgements

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Mohamadi Sarkar

Many thanks to our collaborators: Kevin Ball, Hui Cheng, Josh Karelitz, Andrea Vansickel

Many thanks to our reviewers: Sam Ewusie, Ed Largo, Jack Marshall, Raheema Muhammad-Kah, Lai Wei





 Any  
**Questions?**





# Discussant

FDLI Tobacco and Nicotine Product Regulatory  
Science Symposium March 2023

Dorothy Hatsukami, PhD

Professor of Psychiatry and Behavioral Sciences

Associate Director, Masonic Cancer Center

University of Minnesota



Masonic Cancer Center

UNIVERSITY OF MINNESOTA

Comprehensive Cancer Center designated by the National Cancer Institute

# Disclosures

- Funding from NIDA, NCI and FDA
- None of my comments reflect the opinion of these agencies



Masonic Cancer Center

UNIVERSITY OF MINNESOTA

Comprehensive Cancer Center designated by the National Cancer Institute

# What do we know and not know about flavors?

Flavors are preferred by people who smoke (PWS) and this preference grows over time.

*However, are flavors essential?*

The results are inconclusive

# Scientific Framework

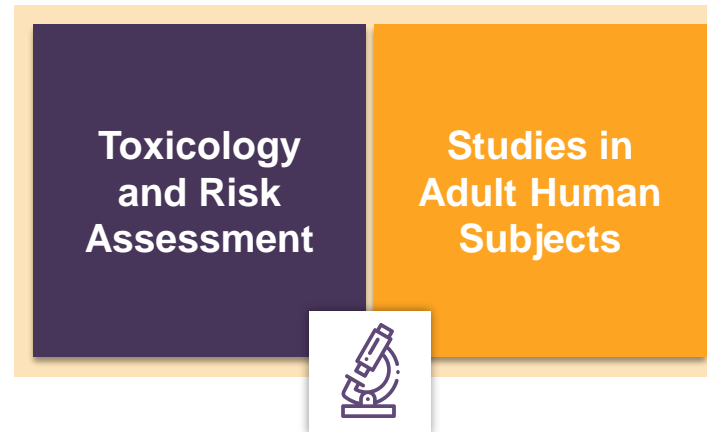
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### THE PRODUCT

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- 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

# Human studies we need

- Randomized clinical trials: Flavors by nicotine dose
- Natural experiments: States that have banned flavors vs. allowed flavors
- Impact of availability of flavors on different populations of PWS
- Communications approaches to promote complete switching (e.g., does advertising the use of nicotine pouches “Anywhere, Anytime” convey complete switching?)



1,650 *per*

© 2020 Heile Innovations LLC

**WARNING: This product contains nicotine.  
Nicotine is an addictive chemical.**

In the moments that matter,  
satisfaction is still an option.

Enjoy the convenience of on!<sup>®</sup> nicotine pouches.  
Your smoke-free alternative.



**on!**  
NICOTINE POUCHES

SHOP ONLINE

Site limited to tobacco consumers  
21 years of age or older.

The advertisement features a background image of four people (two men and two women) sitting around a wooden table in a restaurant or bar, engaged in conversation and holding drinks. The table is set with various dishes and beverages. The overall atmosphere is warm and social.

Figure 1 Marlboro website capture 11/04/2020 (Source: <https://www.marlboro.com>).

# Should manufacturers get in the business of helping people get off the pouch?



Masonic Cancer Center

UNIVERSITY OF MINNESOTA

Comprehensive Cancer Center designated by the National Cancer Institute

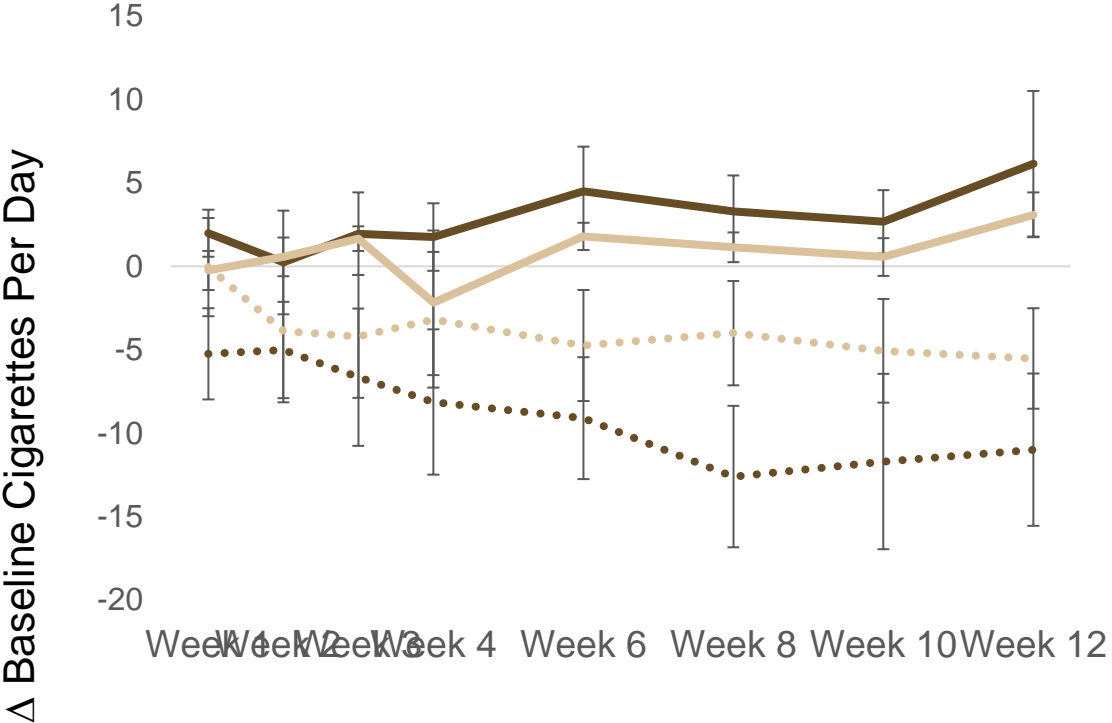
# Forecasting the future

- Human studies examining how the products will fare with forthcoming product standards (menthol ban, nicotine reduction in combustible tobacco)
- Equity focus





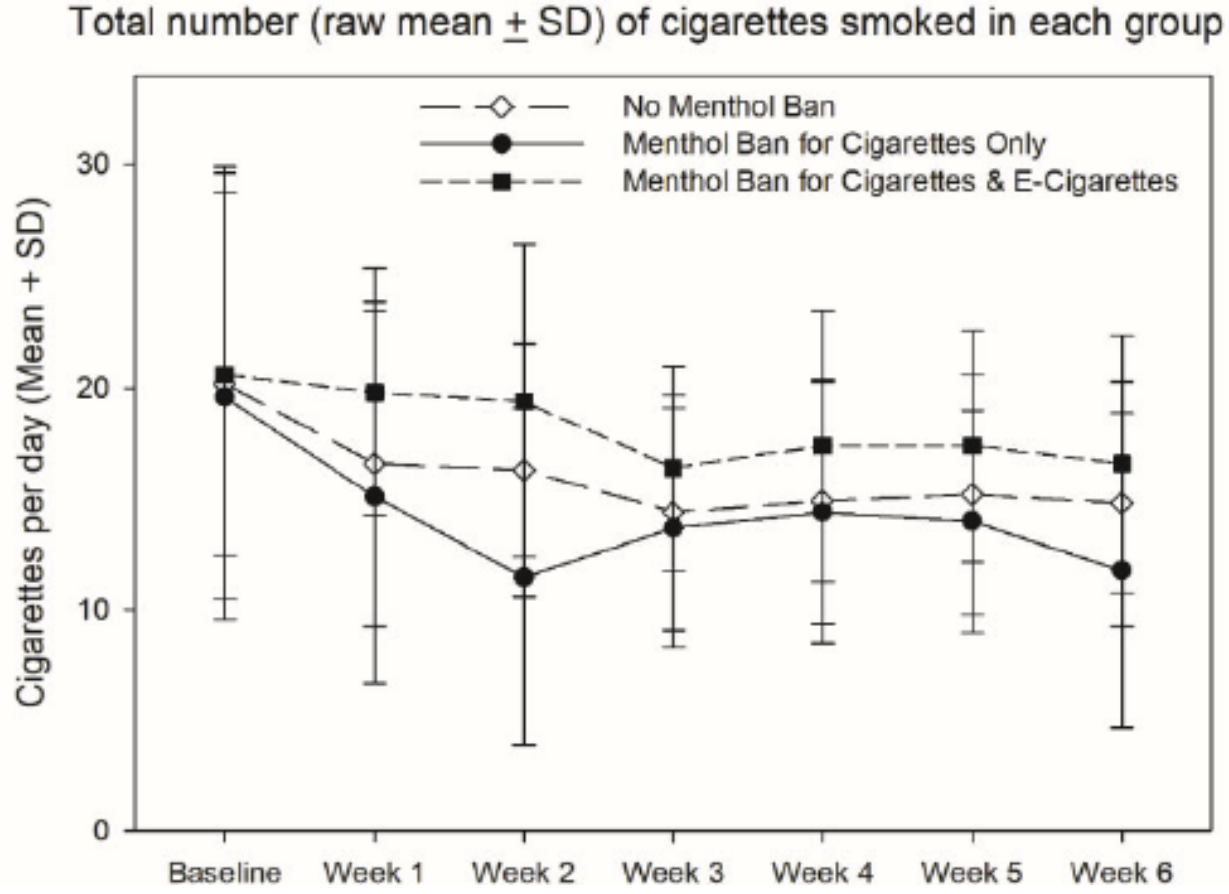
# Cigarettes Per Day: NPS and menthol ban



**Cigarette Nicotine** × **E-liquid Flavor Availability**

- NNC **All** (fruit, dessert, menthol, tob)
- NNC **Only tobacco** (menthol, tobacco)
- ⋯ VLNC **All** (fruit, dessert, menthol, tobacco)
- ⋯ VLNC **Only tobacco** (menthol, tobacco)

White et al., Prev Med, 2022



Kotlyar et al., Prev Med, 2022

# Reducing uptake among youth preemptively

- Marketing and labeling
- Packaging
- Risk communication



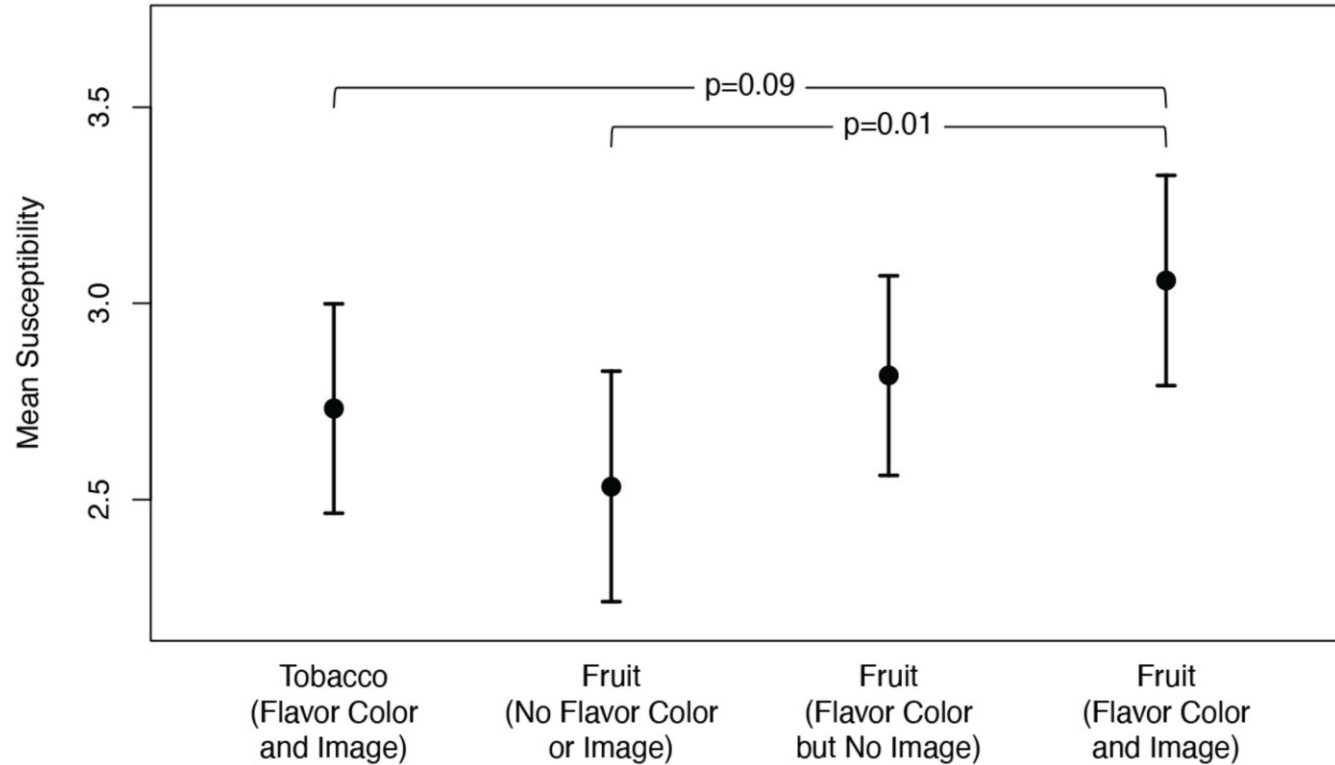
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# Results-Susceptibility

*Mean Susceptibility (with 95% Confidence Intervals) by Flavor and Flavor Representation*



**Condition 4**  
(Fruit, Flavor Color, Flavor Image)



**Condition 2**  
(Fruit, No Flavor Color, No Flavor Image)



# on!® Harm Reduction Opportunity

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

## SEVEN VARIETIES



## 5 NICOTINE STRENGTHS



NO TOBACCO LEAF



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

Elizabeth Becker | Altria Client Services LLC | Regulatory Affairs | FDLI Tobacco & Nicotine Symposium | March 30, 2023 |

# Summary

- Nicotine pouches have the potential to have a dramatic effect on reducing tobacco harm associated with cigarette smoking and smokeless tobacco use.
- Availability of flavors might facilitate complete substitution of cigarettes but still inconclusive.
- Methods to reduce the appeal of flavored products among youth must be examined. It is not sufficient to show that uptake among youth is limited.

