

# Harm Reduction Potential of Oral Tobacco Products

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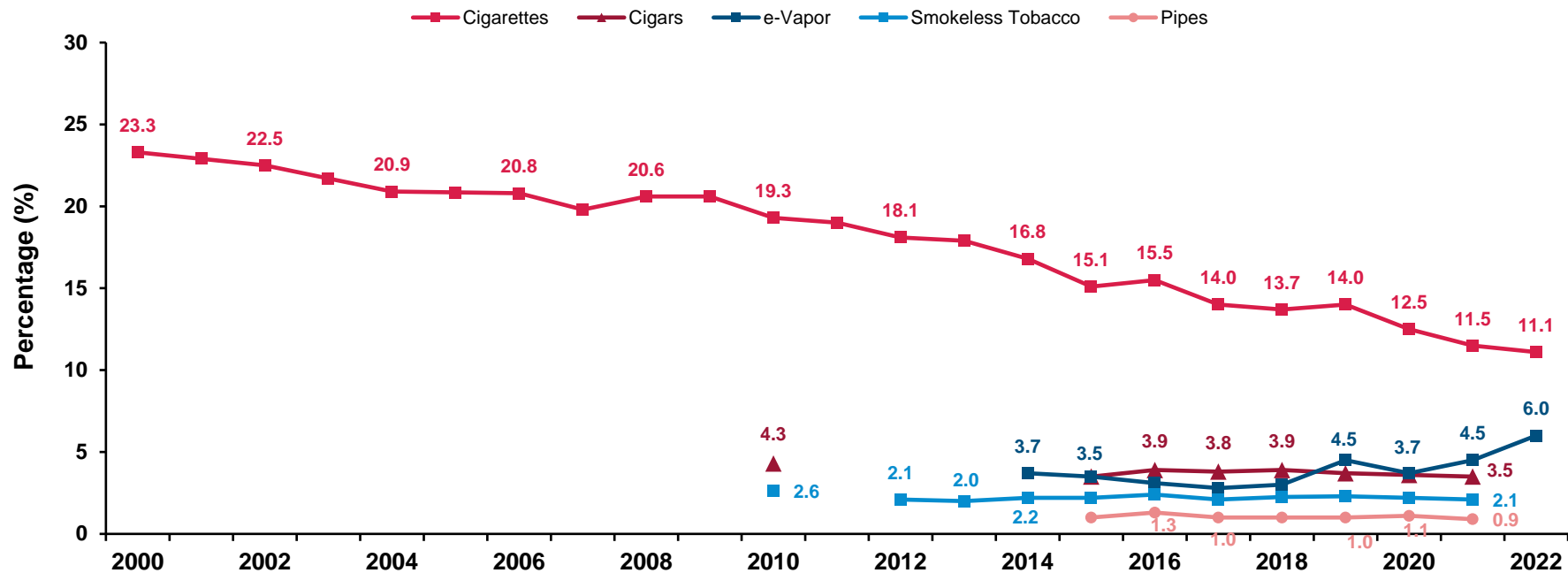


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— FAMILY OF COMPANIES —



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



# 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®\*



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



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

# on!® Harm Reduction Opportunity

on!® pouches have the most variety of any nicotine pouch currently on the 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
- Chemical characterization

## INDIVIDUAL RISK REDUCTION



### EXPOSURE and HEALTH RISK

- Toxicology & Risk Assessment
- Health risk assessment (absolute and relative)
- Human Studies
- Human Factors Assessment

## POPULATION HARM REDUCTION



### IMPACT on the POPULATION

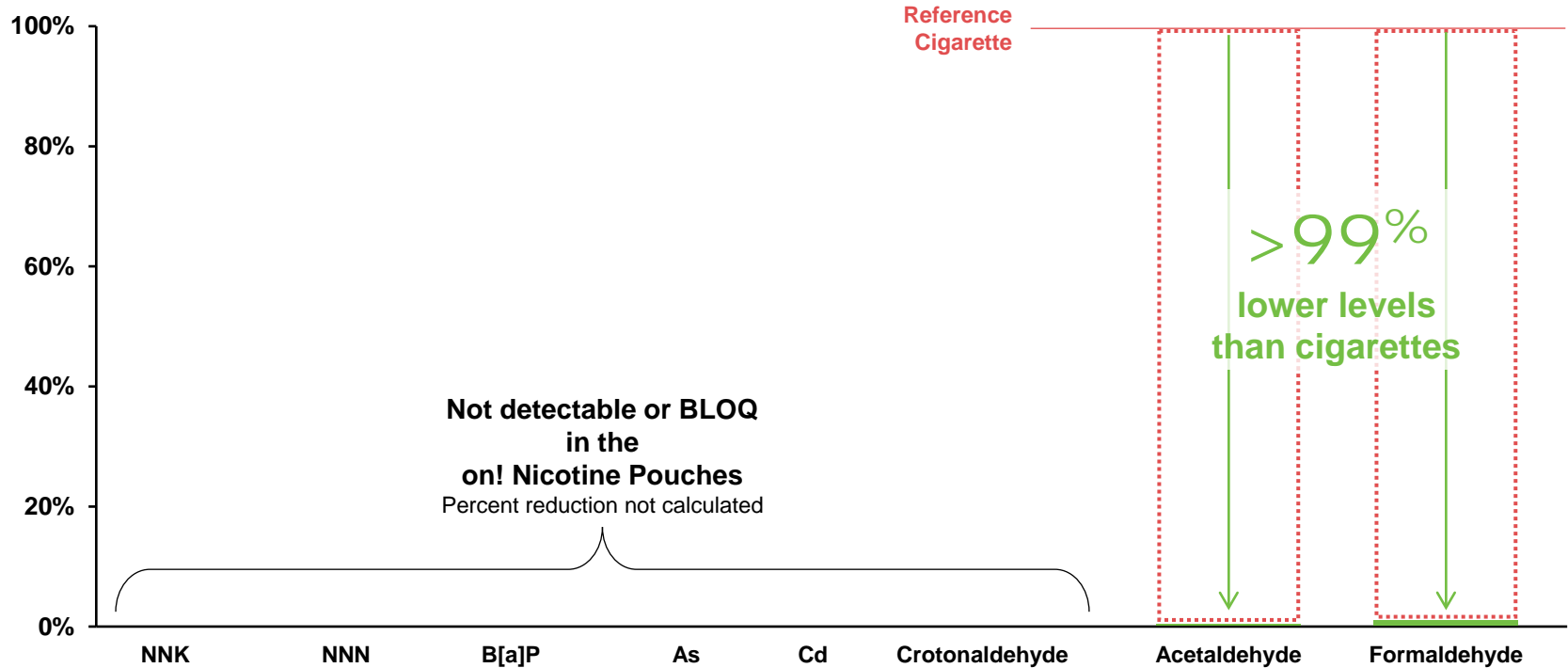
- Risk perceptions (absolute and relative)
- Impact of product on users
- Impact on non-users
- Overall impact on the population
- Environmental Assessment



# HPHCs in on!® Products 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; NNK=4-(methylnitrosamino)-1-(3-pyridyl)-1-butanone; NNN=N-nitrososornicotine.  
Source: Percent reductions based on average HPHC levels in 4 mg on! Mint product compared to cigarette mainstream smoke levels measured under ISO conditions.



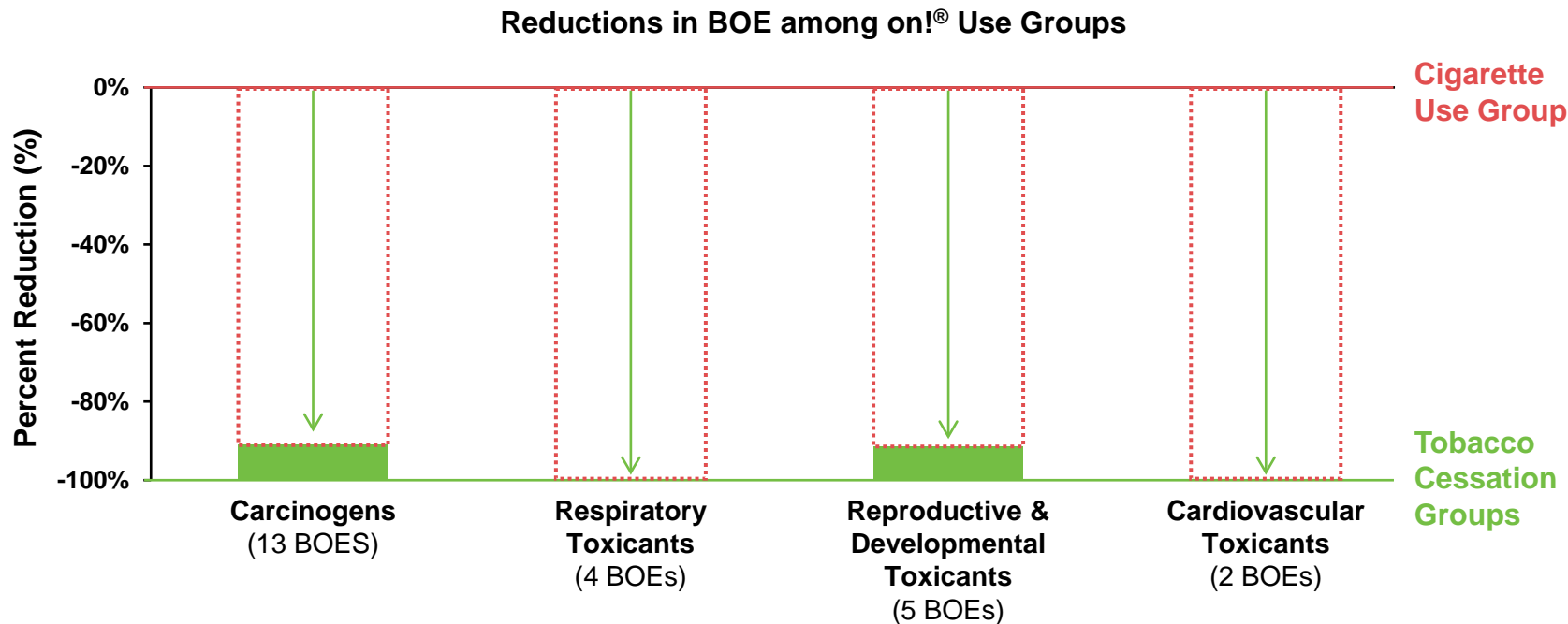
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# Substantial Reductions in Biomarkers of Exposure to HPHCs



INDIVIDUAL RISK REDUCTION



Source: ALCS, Based on group Least Square mean ratios from statistical model comparing the Day 7 BOE level after switching to on!® pouches. (Average of three groups: 2mg, 4 mg, 8 mg Mint Pouches) to the BOE level of the continued smoking group (set as 0) and relative to the tobacco cessation group (set as -100%).



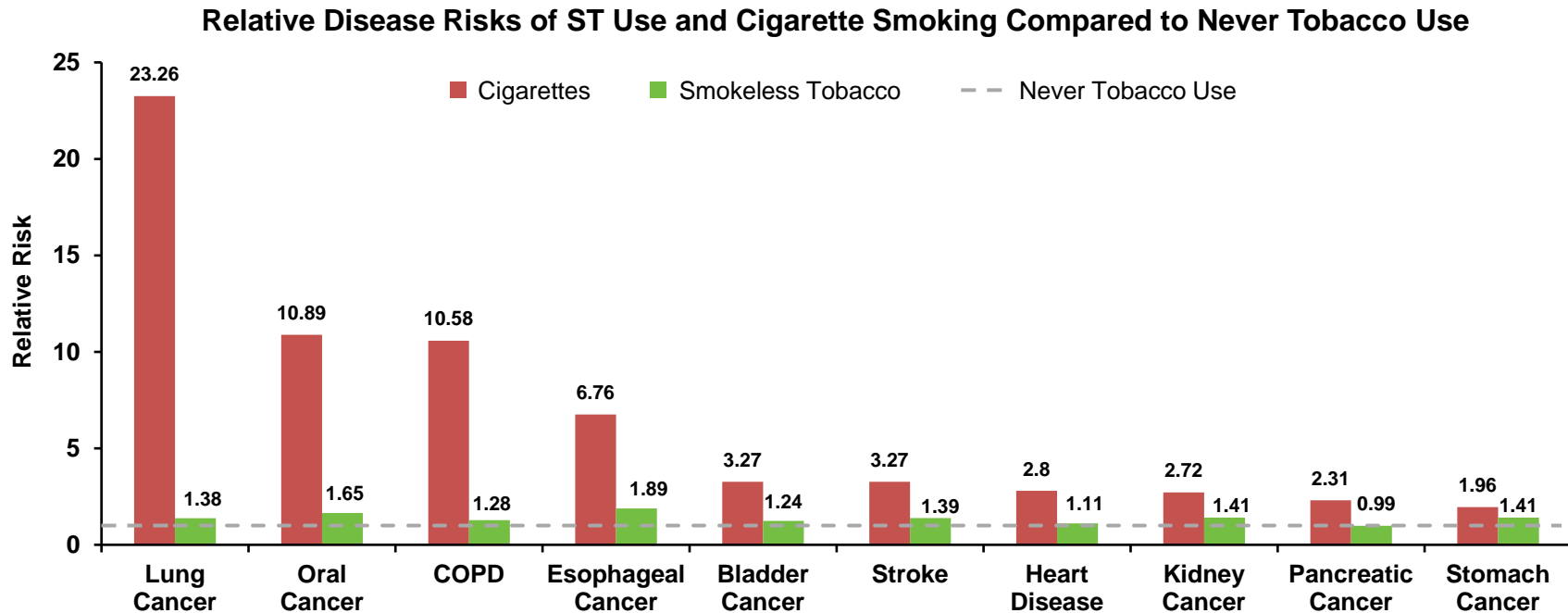
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# Health Risks From Completely Switching to on!® Nicotine Pouches will be Substantially Lower Than Cigarettes



INDIVIDUAL RISK REDUCTION



The relative risk (RR) data for cigarette smoking are obtained from Rostron (2013). Data shown in the figure pertain to RR of male smokers. For ST use, relative cancer risk estimates are from the “smoking-adjusted” results reported in Lee and Hamling (2009); relative risk estimates of heart disease and stroke are from Lee (2007); COPD risk is from CPS-II analysis conducted by Henley et al. (2005).

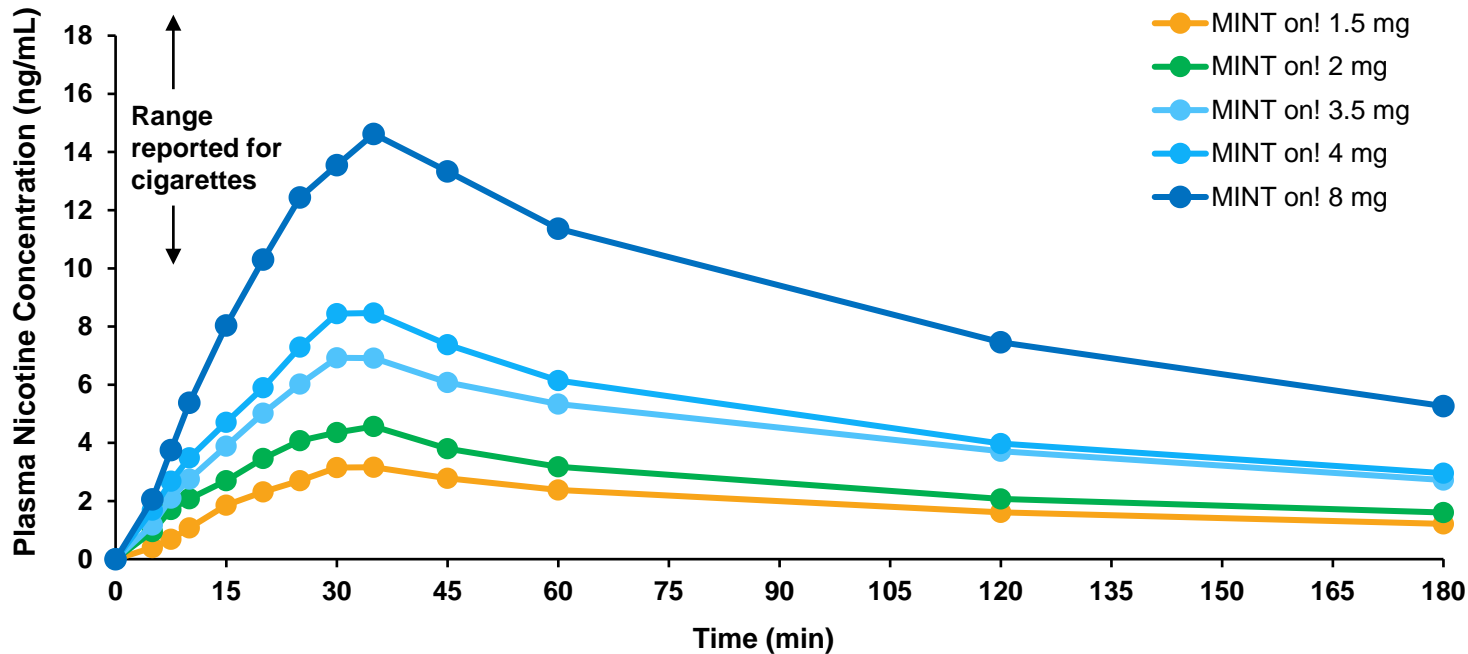


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# The on!® Portfolio Delivers a Wide Range of Nicotine



\*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)



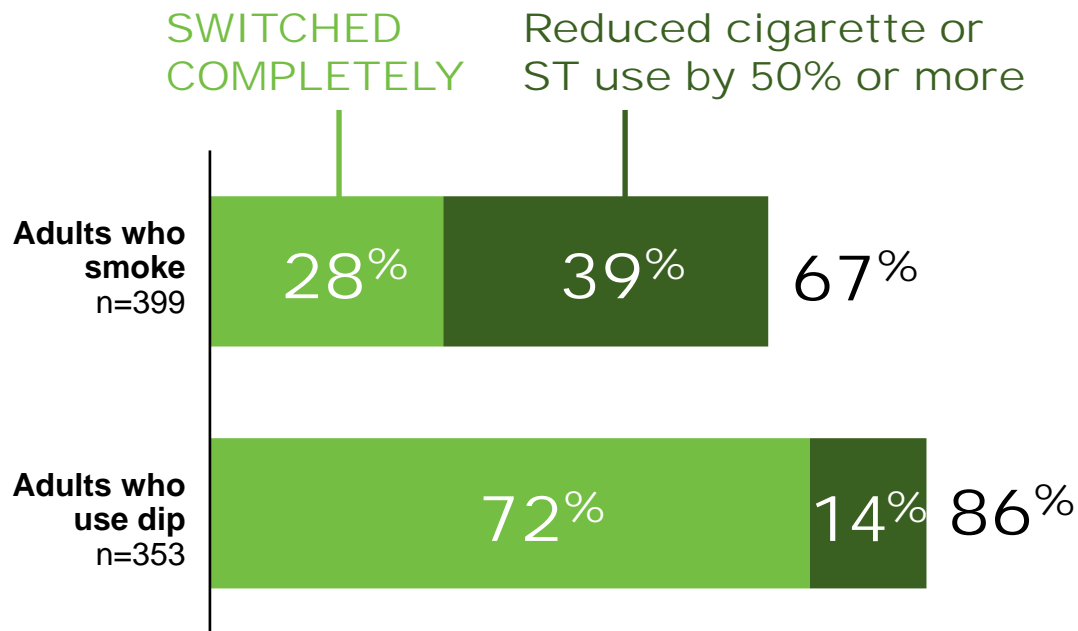
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# Large Proportions of Adults Using Traditional Tobacco Switched or Reduced Consumption



POPULATION HARM REDUCTION



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



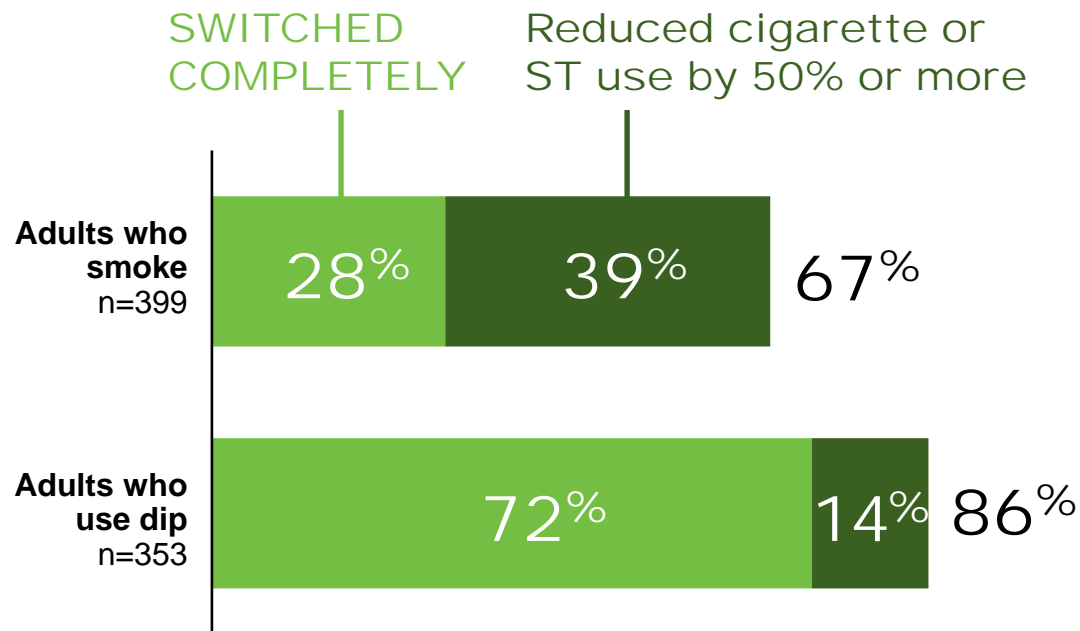
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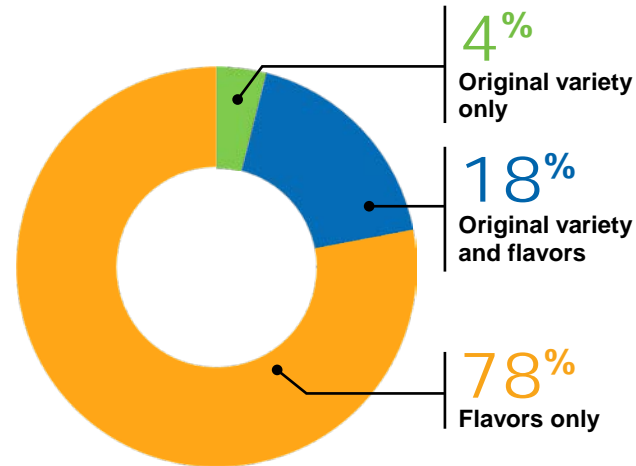
# Large Proportions of Adults Using Traditional Tobacco Switched or Reduced Consumption



POPULATION HARM REDUCTION



Most switchers used flavored on!<sup>®</sup> nicotine pouches



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



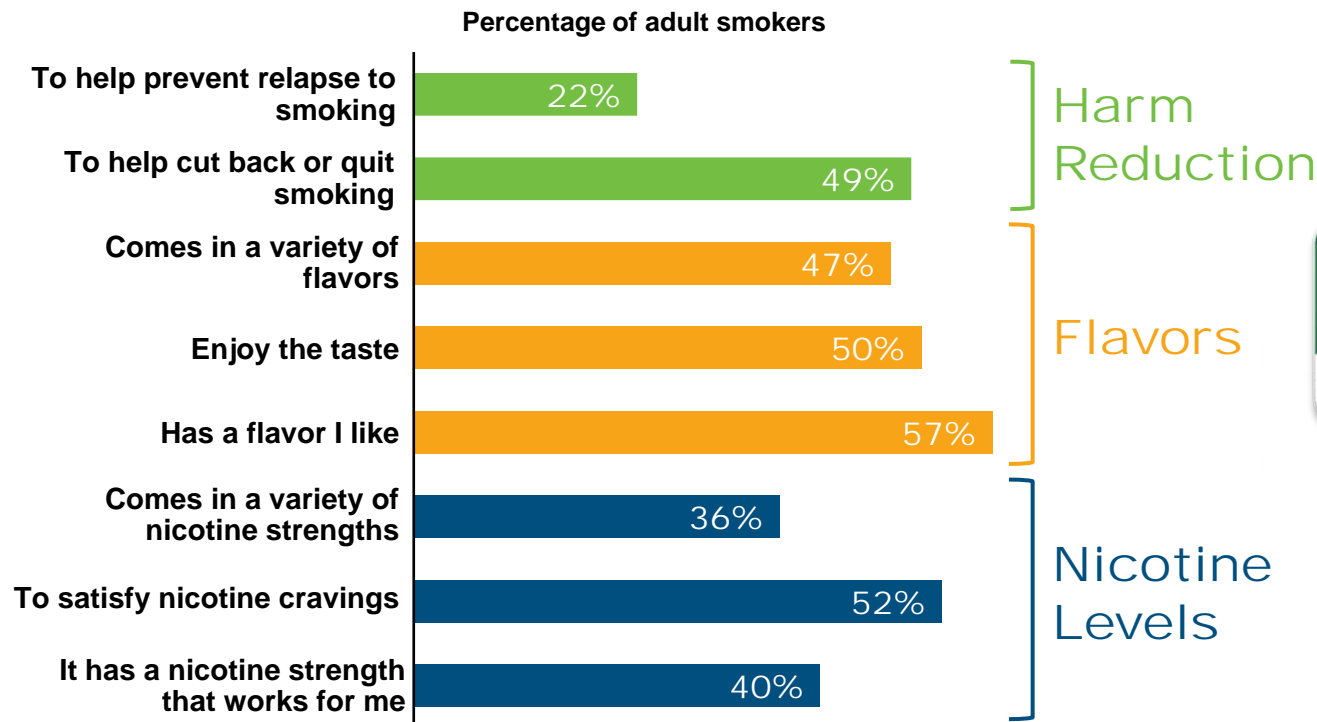
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# Reasons for Future Use of on!® Among Adults Who Smoked



POPULATION HARM REDUCTION



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# Low likelihood of appeal and use on!® Nicotine Pouches among Nonusers of Tobacco Products



POPULATION HARM REDUCTION

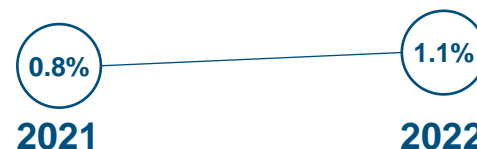
Low likelihood of appeal among nonusers  
and low intentions to try and use

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 Combined<sup>1</sup>



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



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# 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 cigs or ST
- ✓ Low likelihood of use among nonusers, including youth



**Net Population Benefit**

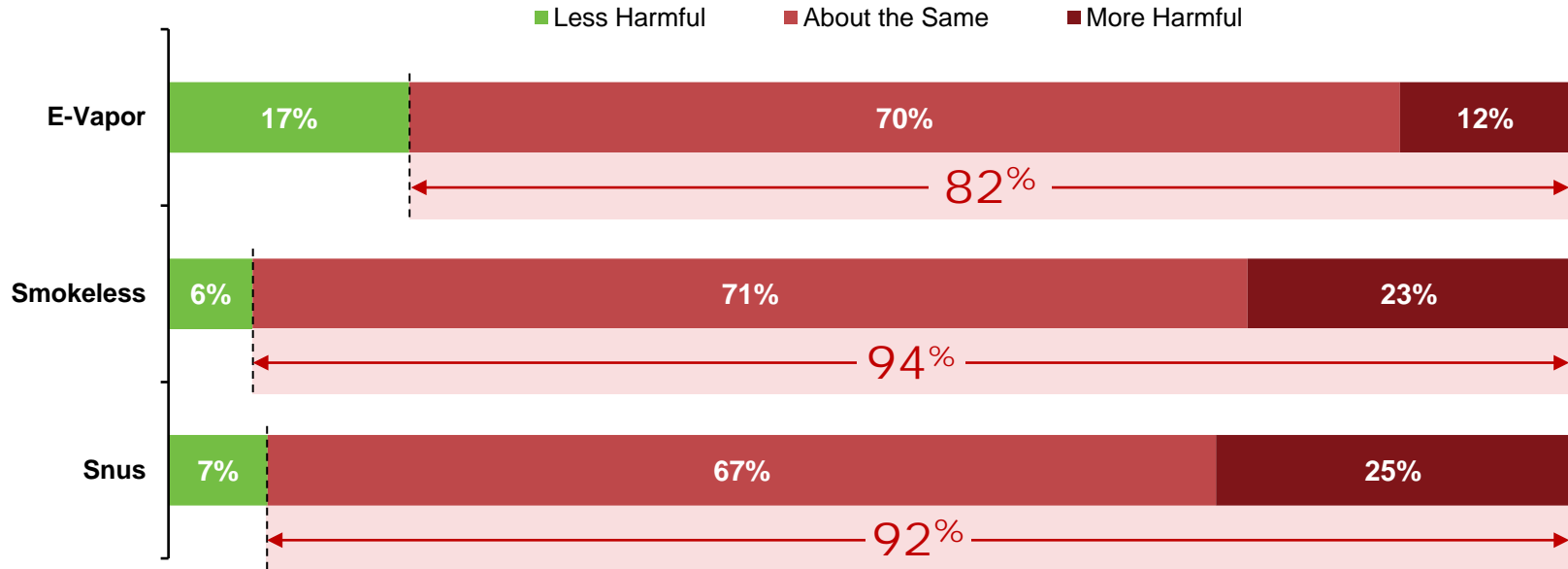
**APPH**

\*Appropriate for the Protection of Public Health



# Vast Majority Believe that Smoke-free Products Are About the Same or More Harmful than Smoking

PATH Wave 5 (2018-2019) Data on Adults Who Smoke Cigarettes



Note: Numbers do not round to 100% because the "not sure" category is not included for the E-vapor and Snus categories due to the relatively small values



# 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](http://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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# 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.



# Advancing Tobacco Harm Reduction



## CHOICES

A variety of FDA-authorized reduced risk products for adults who smoke



## COMMUNICATE

Accurate, non-misleading information about these products to adults who smoke



## CONSISTENTLY

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

