



A Conceptual Framework for Realizing Tobacco Harm Reduction in the United States: Current Progress and Future Direction





Special Thanks to My Collaborators



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The U.S. is on the way to becoming a smoke-free nation

Adult (21+) smoke-free product use  increased ~60% in the past 7 years*



Smoking rates have fallen below 10%**



>25 million adults still smoke cigarettes

Most young adults have moved away from smoking in favor of smoke-free products, though some receptivity to cigarettes remains

The availability of smoke-free products remains important to meet persistent nicotine demand



There are many threats to Tobacco Harm Reduction (THR)

Flavor bans/
de facto bans

Misperceptions
of nicotine risk
vs. smoke

Underage use
of smoke-free
products

Illicit products that skirt
the regulatory system

Long arduous tobacco product
application processes

and more...

Incredible progress toward Tobacco Harm Reduction has been made in recent years
MANY things need to happen to fully realize a smoke-free future

Continued progress requires a sustainable framework
and a reimagining of what a smoke-free future looks like

*ALCS Adult Tobacco Consumer Tracker (ATCT) 2018-2025

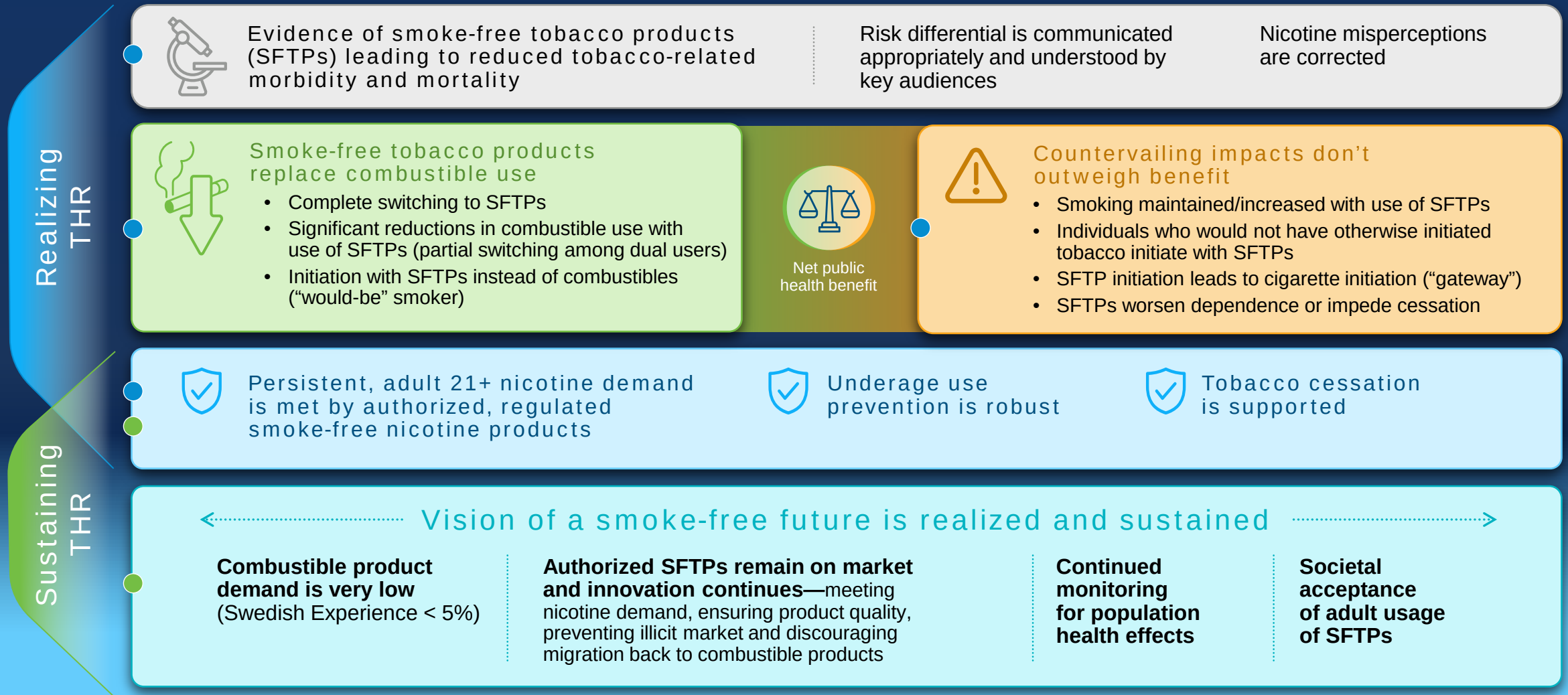
**Interactive Biannual Early Release Estimates; National Center for Health Statistics, National Health Interview Survey: [Biannual Early Release tables](#)



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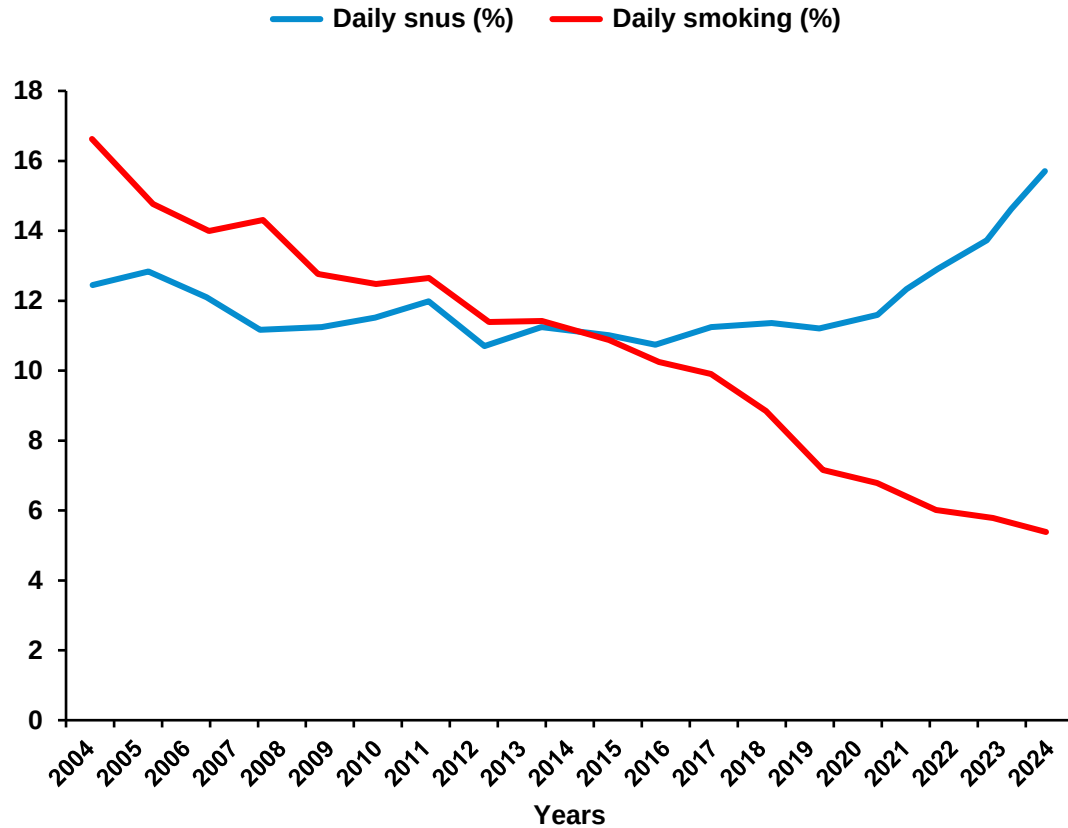
Sustainable Tobacco Harm Reduction Framework



True Tobacco Harm Reduction is Possible

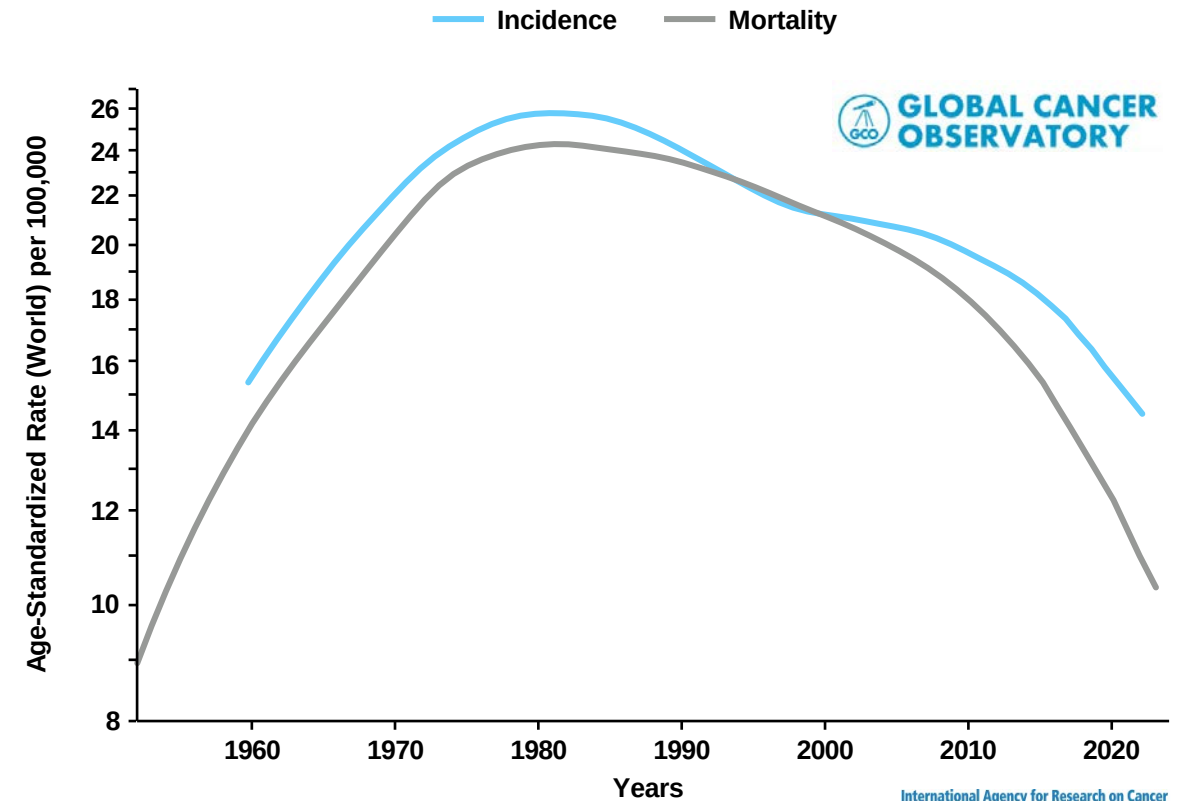
Swedish Experience

20-Year Look: Prevalence of Daily Tobacco Smoking and Daily Snus Use Among the Swedish Population Aged 16 to 84*



*Source: [Use of tobacco and nicotine products \(self-reported\) by age, sex, and year. Share \(percent\). Public health data](#)

Age-Standardized Rate (World) per 100,000 Incidence and Mortality (Males, Lung, Sweden)



Lines are smoothed by the LOESS regression algorithm (bandwidth: 0.25). Rates are shown on a semi-log scale. Cancer Over time |

IARC: <https://gco.iarc.who.int/overtime> Data version: Version 2.1; © All Rights Reserved 2025

International Agency for Research on Cancer

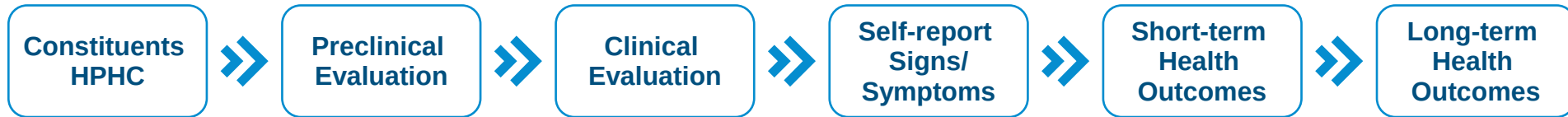


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Longer-term Epidemiological Evidence of the Relative and Absolute Health Risks of Smoke-free Products Must Be Captured, Critically Assessed and Disseminated

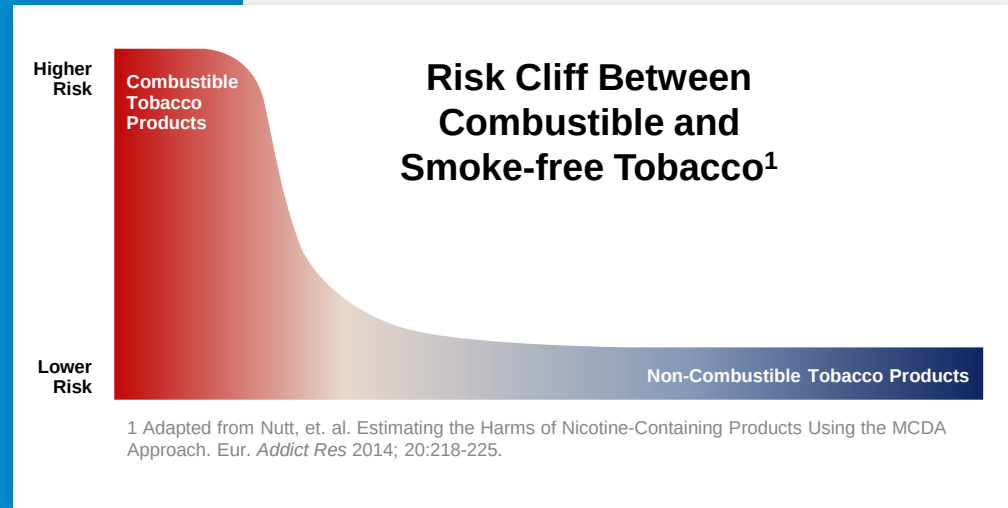


Evidence of smoke-free tobacco products leading to reduced tobacco-related morbidity and mortality



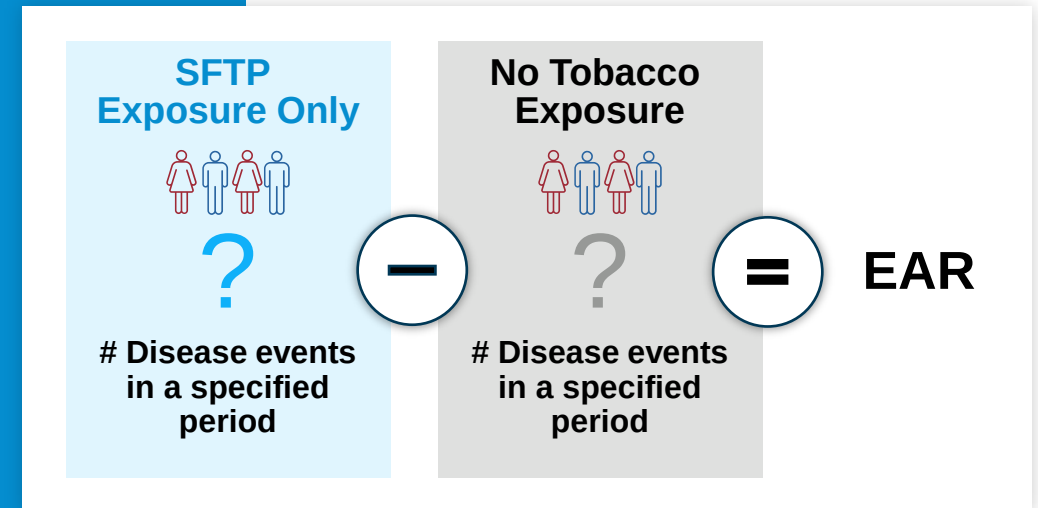
RELATIVE Health Risks

Evidence for risk cliff currently driven by constituent reduction and lowered exposure.
Will reductions in exposure lead to lowered disease risk?



ABSOLUTE Health Risks

What is the Excess Absolute Risk (EAR) of prolonged exposure to Smoke-Free Tobacco Products (SFTPs) ONLY, including any potentially unknown or unanticipated health risks?



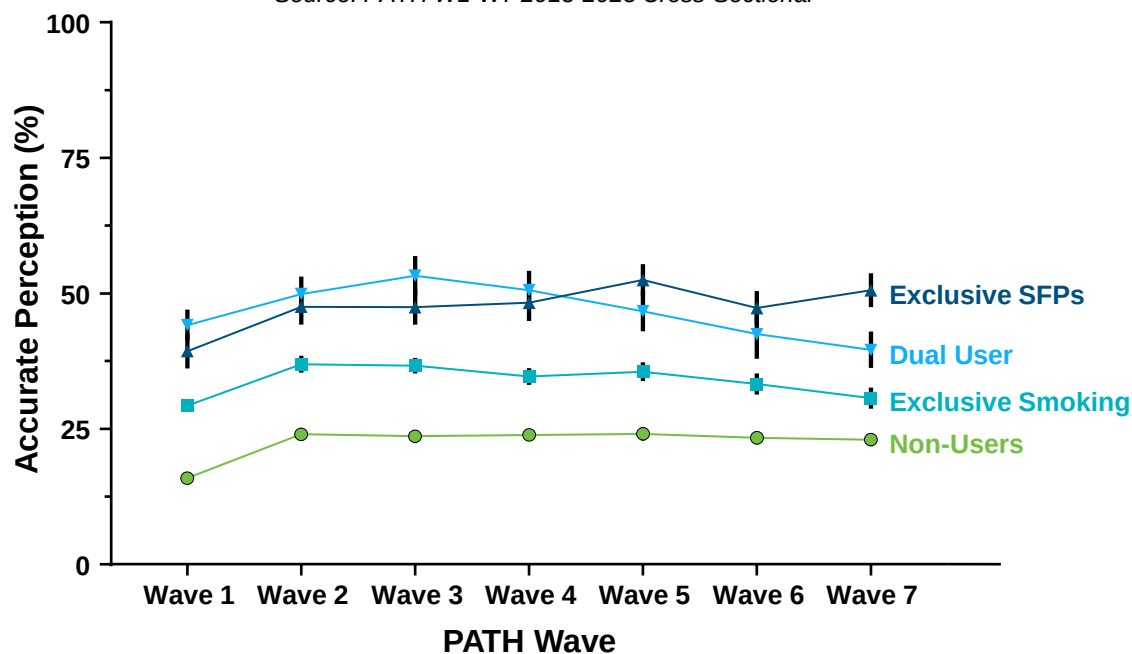
Risk Misperceptions Prevent ATCs From Switching to Smoke-free Products — Most Adults, Regardless of Tobacco Use, Have Inaccurate Perceptions of Nicotine Risk



Evidence of smoke-free tobacco products leading to reduced tobacco-related morbidity and mortality – Nicotine Misperceptions are Corrected

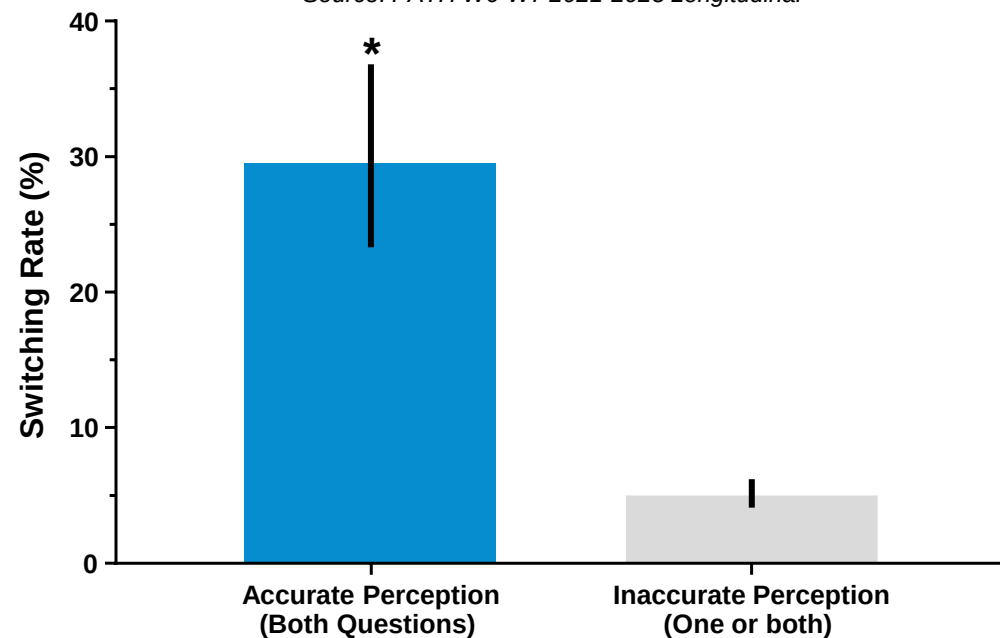
Percentage of Adults (21+) w/Accurate Nicotine Harm (Cancer Causing) Perceptions Across Four Exclusive Use Groups

Source: PATH W1-W7 2013-2023 Cross-Sectional



Adults (21+) Smoke-Free Product Switching Rates by Accurate Perception of Both Nicotine as Causing Cancer & Relative Harm of EV vs. CC

Source: PATH W6-W7 2021-2023 Longitudinal



Data Source: ALCS Analysis of PATH RUF Data (Internal docket: 2025-AP-02: E-THR).

Weighted PATH W1-W7 cross-sectional analysis of adult's (21+) accurate perceptions of nicotine harm across 4 exclusive use groups.

Accurate perceptions of nicotine harm: Answering "probably not" or "definitely not" to nicotine in cigarettes as being primary cause of cancer;.

Data Source: ALCS Analysis of PATH RUF Data (Internal docket: 2025-AP-02: E-THR).

Weighted longitudinal analysis of PATH W7 switching rates among W6 Adult (21+) ESTD Smokers as a function of accurate vs. inaccurate combined perception of both nicotine harm and relative harm of EV vs. Cigarettes.

Switching rate for W6 established smokers with accurate perceptions of both = 29.6% vs. 5.1% among W6 established smokers with at least one inaccurate perception.

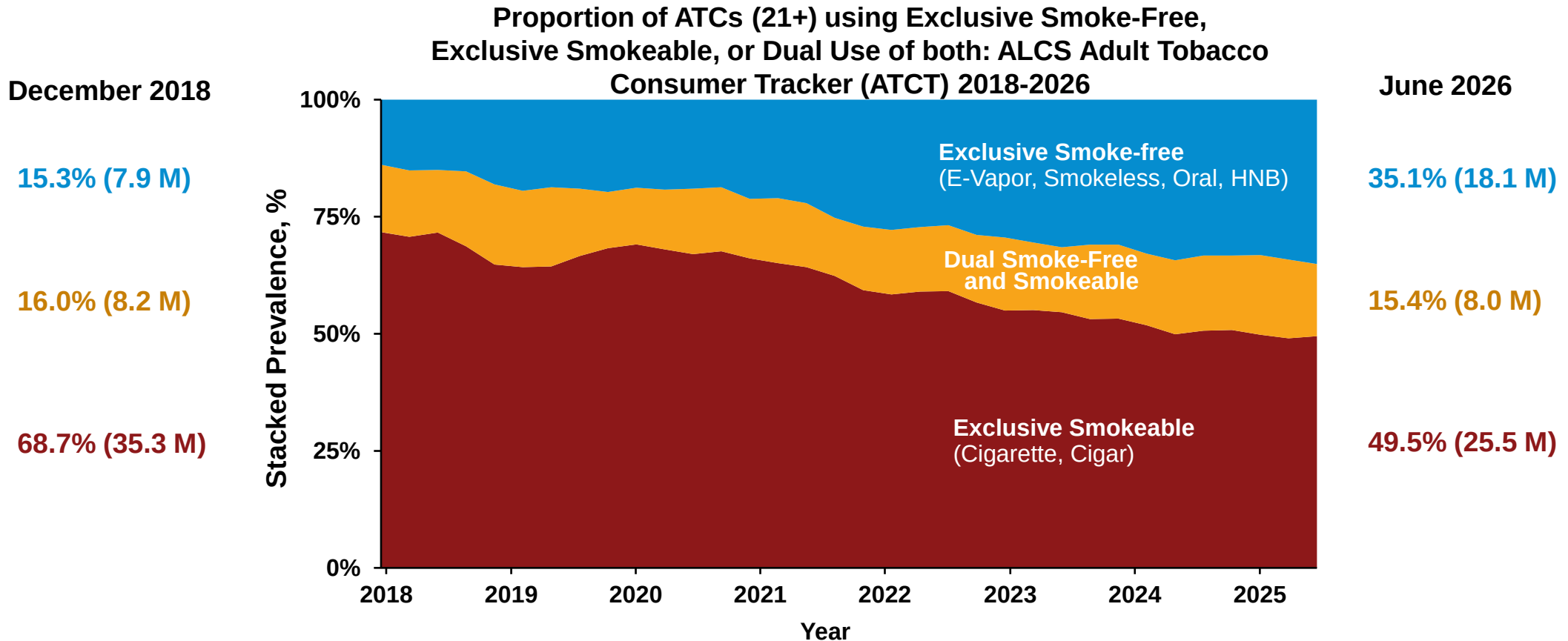


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The Proportion of Adult Tobacco Consumers 21+ Using Smoke-free Products Exclusively Rose from About 14% in 2018 to 33% in 2025



Smoke-free tobacco products replace combustible use



Source: Age 21+, ATCT (6mm distribution) RA Jul 2017 to Sep 2025 Numbers may not foot due to rounding. %'s computed on population weights. HNB has data only from Jan 2020. OTPs include hookah, chew, pipe tobacco, etc. Exclusive use of OTPs is not included in base for analysis. Use of OTPs is considered in the count of product usage (as 'Other') in all analysis. Internal docket: 2025-AH-64.
-Exclusive Smoke-Free (E-Vapor, Smokeless, Oral, HNB) | Dual Smoke-Free and Smokeable | Exclusive Smokeable (Cigarette, Cigar)



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Smoke-free Products Help People Stop, Reduce, or Avoid Cigarette Smoking



Smoke-free tobacco products replace combustible use

Do Smoke-free Products Promote...

...complete switching?



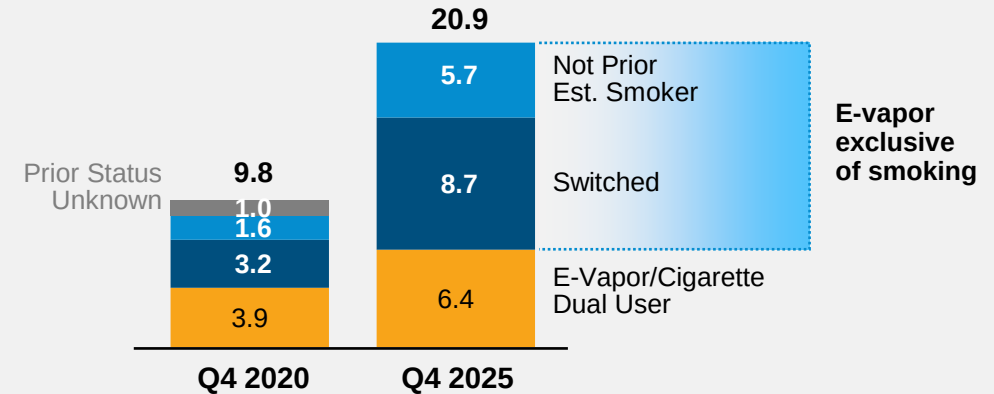
- Strong evidence for switching
- Approximately 1 in 4 established adult smokers who still use tobacco have switched to smoke-free products (24.4%; Q4 2025; ALCS ATCT)
- Current e-vapor users who switched from cigarettes more than doubled since 2020 (ALCS ATCT)

...cigarette reduction?



- Dual users increasingly smoking less
- Reduction in cigarettes per day is associated with reductions in exposure
- Dual users more likely to switch than exclusive cigarette smokers

Adult (21+) E-Vapor Population By Smoking Status (ATCT, in millions)



Cigarette Usage among Adult (18+) E-Vapor+Cigarette Dual Users (PATH)

	WAVE 1 (2013/14)	WAVE 7 (2022/23)
n	680	719
Percentage of DU who smoke cigarettes everyday	76%	57%
Number of days that some day users smoke cigarettes	13.4	8.5

Source: Top-Source: Altria Client Services LLC Adult Tobacco Consumer Tracker (ALCS ATCT)

Age 21 or older, past 30-day usage estimates reported at each quarter are made by combining data from the most recent 12 months up to the end of the reporting quarter.

Results are based on population weights. Numbers may not foot due to rounding.

Bottom-ALCS analysis of PATH Waves 1-7.; Dual Users defined as reporting e-vapor and cigarette use every day or some days in the past 30 days and met established use criteria (100+ cigarettes or used e-vapor fairly regularly)



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Smoke-free Tobacco Products Do Not Impede Cessation or Worsen Tobacco Dependence



Countervailing impacts don't outweigh benefit

Do Smoke-free Products Impede Cessation or Worsen Dependence?

Current evidence suggests that e-vapor may be associated with **lower dependence potential than cigarettes**

Cessation rates tend to be higher for e-vapor and SFP users than exclusive cigarette smokers

Cigarette smokers who switch to SFPs have higher tobacco cessation rates than those who remain cigarette smokers at subsequent follow-up

Baseline (WAVE 6) Tobacco User Group and Dependence Score with Cessation Outcomes at Follow-up (WAVE 7) (PATH, 18+)

WAVE 6	n	WAVE 6 Tobacco Dependence Index# Score	WAVE 7 No use in P30D	WAVE 7 Quit All Tobacco
E-Vapor Only	1264	1.35	19.0%	14.1%
Smokeless Only	338	2.45	17.6%	11.7%
Cigarette Only	3496	2.79	9.0%	6.1%
Cigarette and E-Vapor DU	477	2.50	5.0%	4.8%

Baseline (Wave 6) Tobacco User Group and Cessation Outcomes at Follow-up (WAVE 7) (PATH, 18+)

WAVE 6	n	WAVE 7 Quit Cigarettes and SFPs*
Exclusive SFP (Switchers)*	1470	19.3%
Cigarette (no SFP use)*	3738	7.8%
Cigarette and SFP DU	699	6.7%

Source: Top- ALCS Analysis of PATH (Longitudinal) Wave 6 to Wave 7 ((RWE_Dependence_05202025.pptx))
Bottom-ALCS Analysis of PATH (Longitudinal) Wave 6 to Wave 7.Internal docket: 2025-AP-03: LTS-THR).

#e.g., Strong et al., 2020. Predictive validity of the adult tobacco dependence index: findings from waves 1 and 2 of the Population Assessment of Tobacco and Health (PATH) study. [Predictive validity of the adult tobacco dependence index: Findings from waves 1 and 2 of the Population Assessment of Tobacco and Health \(PATH\) study - ScienceDirect](#)

*Switchers defined as ever having smoked cigarettes; cigarette smokers could use other combustibles; Wave 7 non-user of cigarettes and SFPs defined as non-current user of either product .



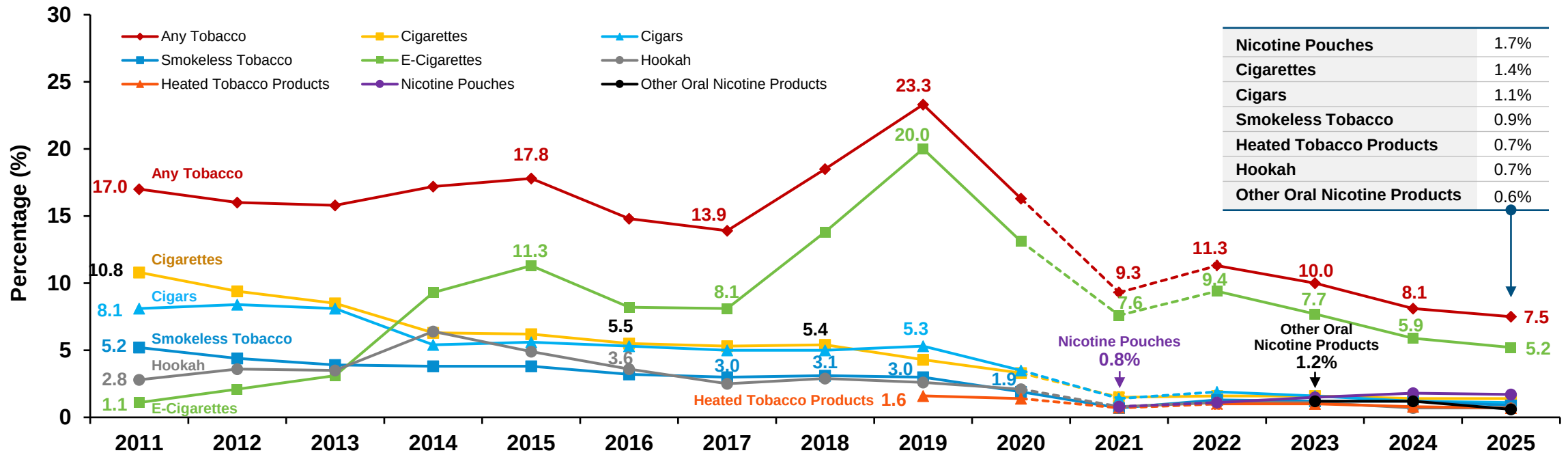
Youth Use of Tobacco/Nicotine Products is in Decline—Cigarette Smoking is at an All Time Low—We Must Remain Vigilant



Underage use prevention is robust

Current Tobacco Product Use Among MIDDLE AND HIGH SCHOOL STUDENTS Combined

National Youth Tobacco Survey, 2011-2025



Sources: ALCS analysis of NYTS 2011-2021, Tobacco Product Use Among Middle and High School Students — United States, 2022, Tobacco Product Use Among U.S. Middle and High School Students — National Youth Tobacco Survey, 2023, and Tobacco Product Use Among Middle and High School Students — National Youth Tobacco Survey, United States, 2024, ALCS analysis of NYTS 2025.

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-), nicotine pouches (2021-), and other oral nicotine products (2023-) 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. In 2023, dissolvable tobacco products were reclassified from smokeless tobacco to other oral nicotine products. Other oral nicotine products were defined as lozenges, disks, tablets, gums, dissolvable tobacco products, and other products. Dashed lines represent changes in methodology that prevent comparisons across the years.



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To Preserve Smoke-Free Product Availability for Adults We Must Prevent Underage Uptake



Underage use prevention is robust

Our vigilance is key to THR

underage use monitoring and prevention efforts must continue

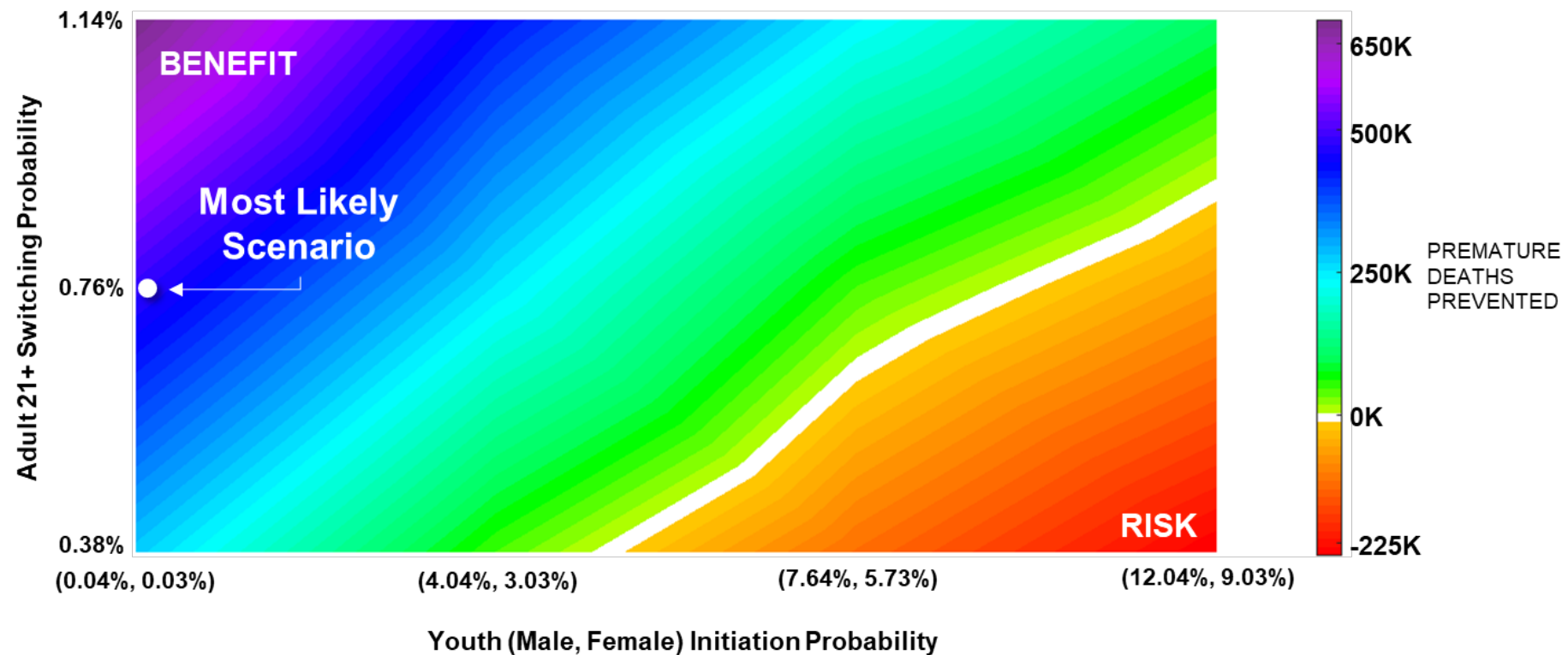
Prevention is possible without prohibition

as demonstrated by the current underage tobacco use landscape

We need to continue to model risks to underage in the context of population health benefits

The risks of underage use cannot outweigh the benefits of SFTP availability*

Example: Tipping point analysis for oral nicotine products



*Source: Thannel T, Muhammad-Kah R, Cheng H, Wei L, Largo E, Sarkar M. (2023) Quantitative risk assessment of the population benefit of adults who smoke switching to nicotine pouch products against the risk of youth initiation using tipping point analysis. Food Drug and Law Institute Tobacco and Nicotine Products Regulation and Policy Conference



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Conclusions and Implications

1

**Need for good epidemiology
and real-world evidence**

2

**Rethink nicotine use/dependence
in tobacco harm reduction context**

3

**Recognize the harm reduction potential
in adult initiation of smoke-free products**

4

**Prevent underage use
to maintain adult smoke-free product access**

5

**Correct misperceptions of nicotine risk
and relative risk of smoke free products**

6

**Objectively weigh risks and benefits
to the population as a whole**





In this Panel

1

**Need for good epidemiology
and real-world evidence**

DEREK POPE

Evidence for the Harm Reduction Potential of ENDS and “Sick Quitter/Switcher” Effects for a Linked Survey and Electronic Health Records Study.

2

**Rethink nicotine use/dependence
in tobacco harm reduction context**

ARIELLE SELYA

Harm Reduction in Never-Smokers?
Rethinking Population Health Implications in an Era of Declining Cigarette Smoking.

3

**Recognize the harm reduction potential
in adult initiation of smoke-free products**

4

**Prevent underage use
to maintain adult smoke-free product access**

ANDREA PATTON

Minimizing Youth Access and Use While Maximizing the Availability of Next Generation Nicotine Products for Adults Who Smoke.

5

**Correct perceptions of nicotine risk
and relative risk of smoke free products**

JESSICA SEIFERT

An Open Door or a Barrier to Entry?
How Risk Perceptions Shape Access in Tobacco Harm Reduction.

6

**Objectively weigh risks and benefits
to the population as a whole**

RYAN SELTZER

From Product to Population:
Estimating Product-Variant Public Health Impacts of Age-Gated Breeze Pro ENDS.

