PMI | U.S.

ZYN MRTP Application

Tobacco Products Scientific Advisory Committee Meeting

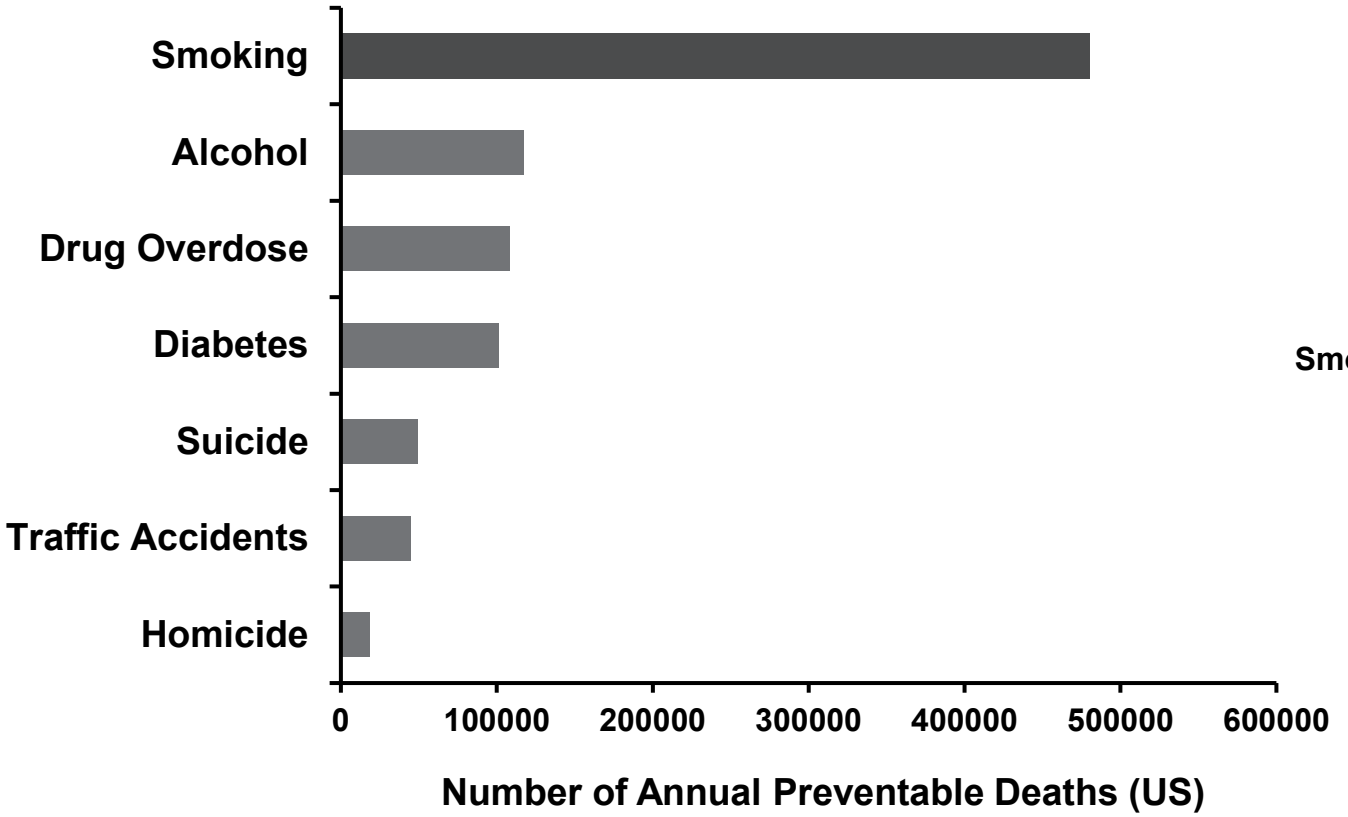
Swedish Match USA, Inc.

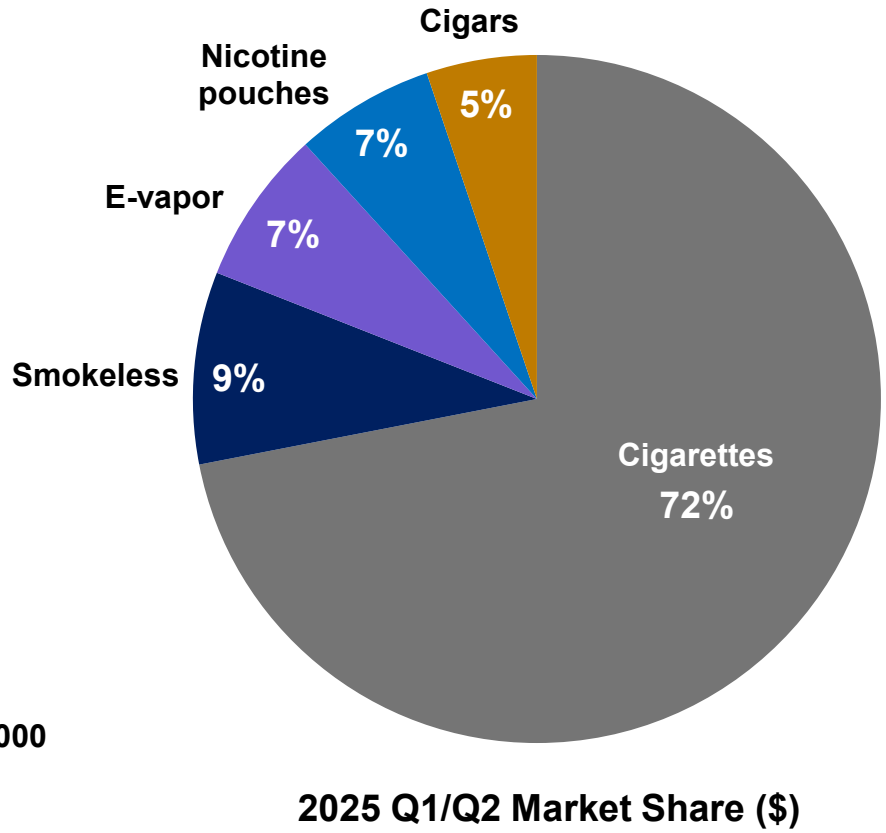
January 22, 2026

Introduction

Keagan Lenihan
Vice President and Chief External Affairs Officer, U.S.

Smoking is the #1 Cause of Preventable Annual Deaths in U.S.





Smoking kills ~500,000 Americans per year

Despite significant declines, there are still ~30M smokers in U.S.

Source: Center for Disease Control Archive – Tobacco Related Mortality

PMI U.S. – Leading Innovator and Manufacturer of FDA-authorized SFPs in the U.S.

For the past 10 years, PMI has been on a mission to create a smoke-free world, and we want to end cigarette smoking because it is the most harmful form of tobacco use

We believe **science** and **innovation** can drive us toward achieving our vision of a smoke-free future, faster

- Invested in the development, scientific substantiation, and commercialization of innovative FDA-authorized smoke-free products
- We do not sell combustible cigarettes in the U.S.

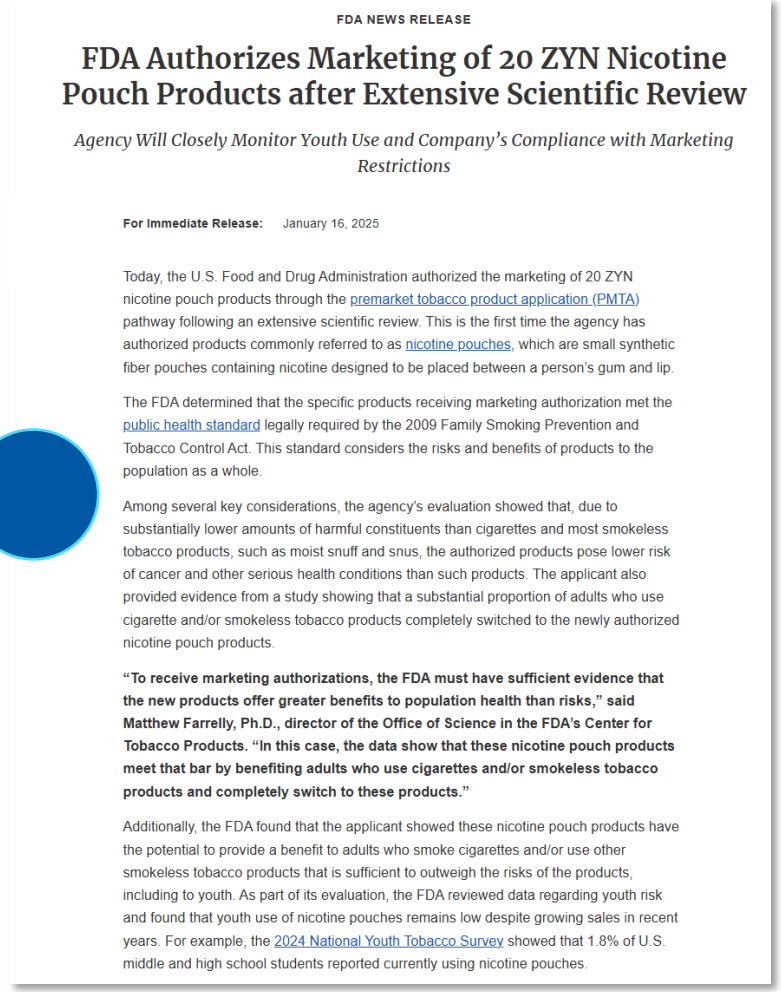
FDA Authorization:
ZYN is Appropriate for the Protection of Public Health

*"The FDA determined that the specific products receiving marketing authorization **met the public health standard legally required** by the 2009 Family Smoking Prevention and Tobacco Control Act."*

*"Among several key considerations, the agency's evaluation showed that, due to **substantially lower amounts of harmful constituents than cigarettes and most smokeless tobacco products,** such as moist snuff and snus, the authorized products pose **lower risk of cancer and other serious health conditions** than such products."*

*"As part of its evaluation, FDA reviewed data regarding youth risk and found that **youth use of nicotine pouches remains low despite growing sales in recent years**."*

- FDA News Release (January 16, 2025)



FDA NEWS RELEASE

FDA Authorizes Marketing of 20 ZYN Nicotine Pouch Products after Extensive Scientific Review

Agency Will Closely Monitor Youth Use and Company's Compliance with Marketing Restrictions

For Immediate Release: January 16, 2025

Today, the U.S. Food and Drug Administration authorized the marketing of 20 ZYN nicotine pouch products through the premarket tobacco product application (PMTA) pathway following an extensive scientific review. This is the first time the agency has authorized products commonly referred to as nicotine pouches, which are small synthetic fiber pouches containing nicotine designed to be placed between a person's gum and lip.

The FDA determined that the specific products receiving marketing authorization met the public health standard legally required by the 2009 Family Smoking Prevention and Tobacco Control Act. This standard considers the risks and benefits of products to the population as a whole.

Among several key considerations, the agency's evaluation showed that, due to substantially lower amounts of harmful constituents than cigarettes and most smokeless tobacco products, such as moist snuff and snus, the authorized products pose lower risk of cancer and other serious health conditions than such products. The applicant also provided evidence from a study showing that a substantial proportion of adults who use cigarette and/or smokeless tobacco products completely switched to the newly authorized nicotine pouch products.

"To receive marketing authorizations, the FDA must have sufficient evidence that the new products offer greater benefits to population health than risks," said Matthew Farrelly, Ph.D., director of the Office of Science in the FDA's Center for Tobacco Products. "In this case, the data show that these nicotine pouch products meet that bar by benefiting adults who use cigarettes and/or smokeless tobacco products and completely switch to these products."

Additionally, the FDA found that the applicant showed these nicotine pouch products have the potential to provide a benefit to adults who smoke cigarettes and/or use other smokeless tobacco products that is sufficient to outweigh the risks of the products, including to youth. As part of its evaluation, the FDA reviewed data regarding youth risk and found that youth use of nicotine pouches remains low despite growing sales in recent years. For example, the 2024 National Youth Tobacco Survey showed that 1.8% of U.S. middle and high school students reported currently using nicotine pouches.

FDA Authorization: Bridging from Snus is Appropriate

Product Format and Use	**Both pouches placed between lip and gum**
Chemical Profile & Toxicology	**Significant reduction of harmful and potentially harmful constituents compared to combusted cigarettes**
Nicotine Delivery	**Similar to smokeless tobacco, NRT, and other oral products**
Use Topography	**Similar number of pouches used per day**

Using *ZYN* instead of cigarettes puts you at a lower risk of mouth cancer, heart disease, lung cancer, stroke, emphysema, and chronic bronchitis.

1. Scientific Evidence Substantiates the Proposed Claim
2. Adults Who Smoke Understand the Proposed Claim
3. *ZYN* Users Switch From or Reduce Cigarette Use
4. Proposed Claim Does Not Increase Appeal to Nonusers

Today's Speakers

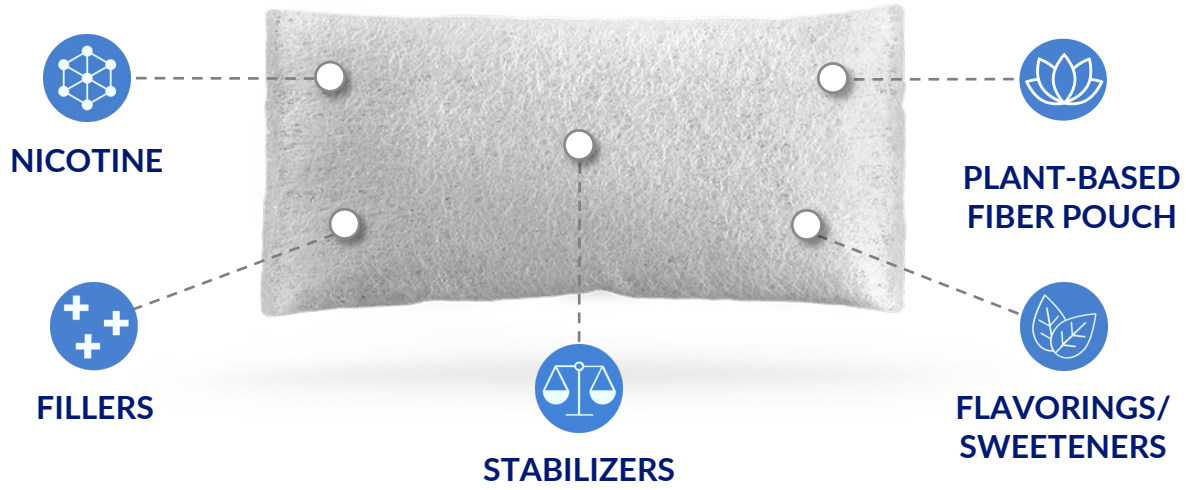
***ZYN* Overview & MRTP Statutory Requirements**	**Keagan Lenihan** Vice President and Chief External Affairs Officer, U.S.
Clinical & Non-Clinical Scientific Assessment	**Dr. Tryggve Ljung** Global Medical Head of Oral Products
Consumer Understanding, Perceptions, & Behavior	**Dr. Jessica Seifert** Head of Regulatory Insights, U.S.
Responsible Marketing and Communicating the Claim & Conclusion	**Keagan Lenihan** Vice President and Chief External Affairs Officer, U.S.

ZYN Overview & MRTP Statutory Requirements

Keagan Lenihan
Vice President and Chief External Affairs Officer, U.S.

ZYN Nicotine Pouches

ZYN is a tobacco leaf-free, spit-free oral nicotine pouch

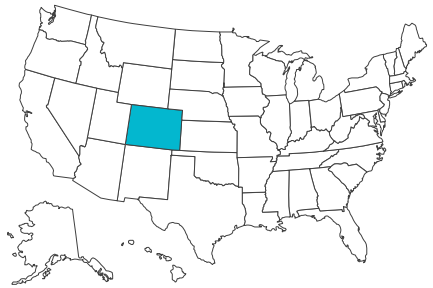


- **Product use very similar to *General Snus***
  - Placed in between the upper lip and gum
- **In the U.S.**
  - Available in two concentrations: 3 mg and 6 mg
  - 10 varieties traditionally found in smokeless
- **Authorized for marketing by FDA on January 16, 2025**
  - As appropriate for the protection of public health

ZYN History

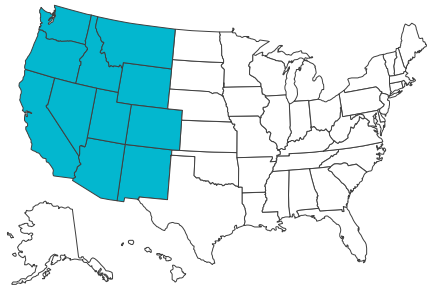
2014

ZYN is test launched in 50 stores in Colorado, US



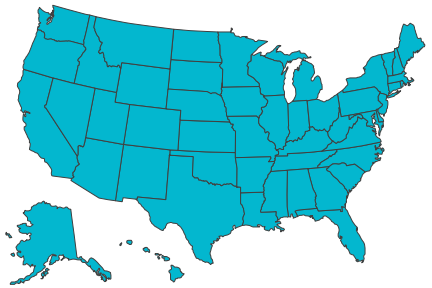
2016

Regional launch of *ZYN* in 11 states in West US



2019

National launch in the US



FDA's Authorization of *ZYN*



"Therefore, to the extent that people who currently smoke cigarettes or use most other smokeless tobacco products switch completely [ZYN] instead of using their current products, **we would expect their health risks to decline substantially**."

– FDA ZYN PMTA TPL Review, Page 6 (2025)

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– FDA ZYN PMTA TPL Review, Page 6 (2025)

"Nearly one quarter (83 of 346 participants) of those who used [ZYN] **completely switched from other tobacco products** and reported exclusive use of [ZYN] by the end of the 10-week prospective study period."

FDA ZYN PMTA TPL Review, Page 27 (2025)

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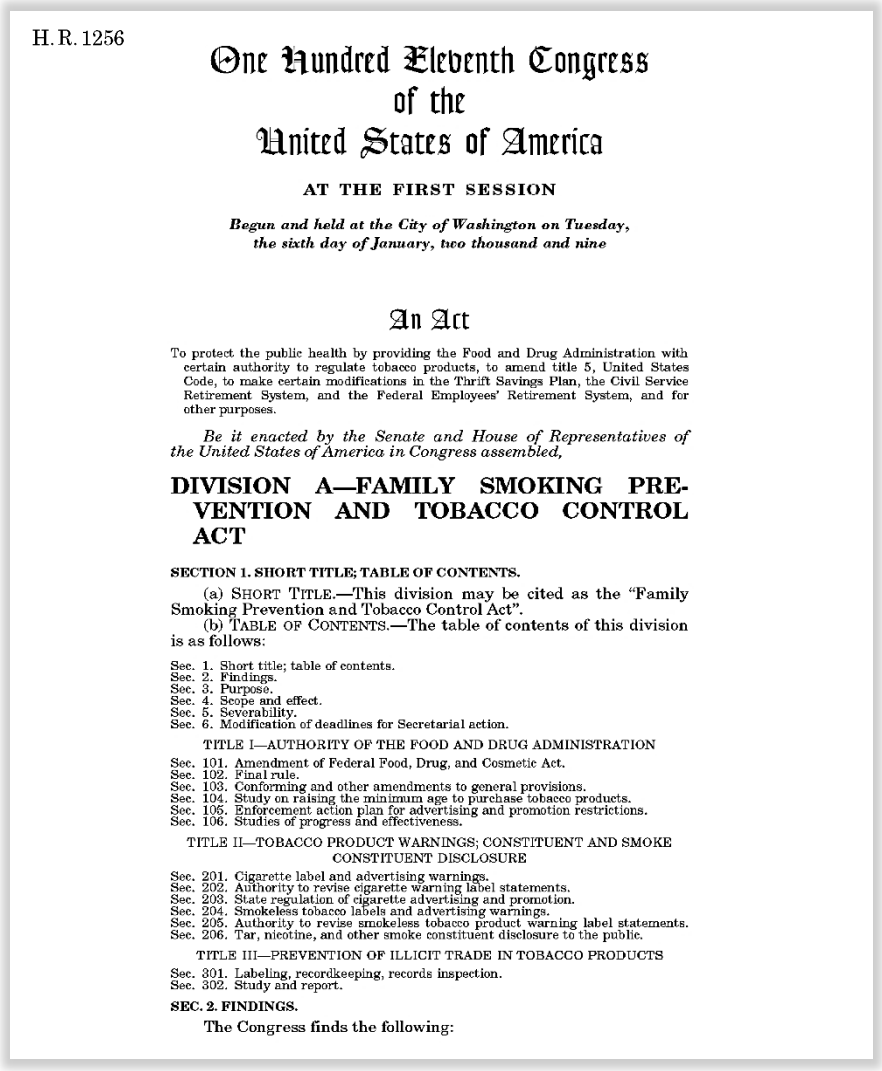
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FDA ZYN PMTA TPL Review, Page 27 (2025)

"FDA expects the **risk of initiation with [ZYN], including initiation among youth, to be low**."

– FDA ZYN PMTA TPL Review, Page 54 (2025)

Family Smoking Prevention and Tobacco Control Act



H. R. 1256

One Hundred Eleventh Congress
of the
United States of America

AT THE FIRST SESSION

Begun and held at the City of Washington on Tuesday, the sixth day of January, two thousand and nine

An Act

To protect the public health by providing the Food and Drug Administration with certain authority to regulate tobacco products, to amend title 5, United States Code, to make certain modifications in the Thrift Savings Plan, the Civil Service Retirement System, and the Federal Employees' Retirement System, and for other purposes.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

DIVISION A—FAMILY SMOKING PREVENTION AND TOBACCO CONTROL ACT

SECTION 1. SHORT TITLE; TABLE OF CONTENTS.

(a) SHORT TITLE.—This division may be cited as the "Family Smoking Prevention and Tobacco Control Act".

(b) TABLE OF CONTENTS.—The table of contents of this division is as follows:

Sec. 1. Short title; table of contents.
Sec. 2. Findings.
Sec. 3. Purpose.
Sec. 4. Scope and effect.
Sec. 5. Severability.
Sec. 6. Modification of deadlines for Secretarial action.

TITLE I—AUTHORITY OF THE FOOD AND DRUG ADMINISTRATION

Sec. 101. Amendment of Federal Food, Drug, and Cosmetic Act.
Sec. 102. Final rule.
Sec. 103. Conforming and other amendments to general provisions.
Sec. 104. Study on raising the minimum age to purchase tobacco products.
Sec. 105. Enforcement action plan for advertising and promotion restrictions.
Sec. 106. Studies of progress and effectiveness.

TITLE II—TOBACCO PRODUCT WARNINGS; CONSTITUENT AND SMOKE CONSTITUENT DISCLOSURE

Sec. 201. Cigarette label and advertising warnings.
Sec. 202. Authority to revise cigarette warning label statements.
Sec. 203. State regulation of cigarette advertising and promotion.
Sec. 204. Smokeless tobacco labels and advertising warnings.
Sec. 205. Authority to revise smokeless tobacco product warning label statements.
Sec. 206. Tar, nicotine, and other smoke constituent disclosure to the public.

TITLE III—PREVENTION OF ILLICIT TRADE IN TOBACCO PRODUCTS

Sec. 301. Labeling, recordkeeping, records inspection.
Sec. 302. Study and report.

SEC. 2. FINDINGS.

The Congress finds the following:

"… to provide new and flexible enforcement authority to ensure that there is effective oversight of the tobacco industry's efforts to develop, introduce, and promote less harmful tobacco products"

-Sec. 3 (4) Purpose

Section 911(g)(1) Modified Risk Products

…the applicant has demonstrated that such product, as it is actually used by consumers, will—

A Significantly reduce harm and the risk of tobacco-related disease to individual tobacco users; and

B Benefit the health of the population as a whole taking into account both users of tobacco products and persons who do not currently use tobacco products

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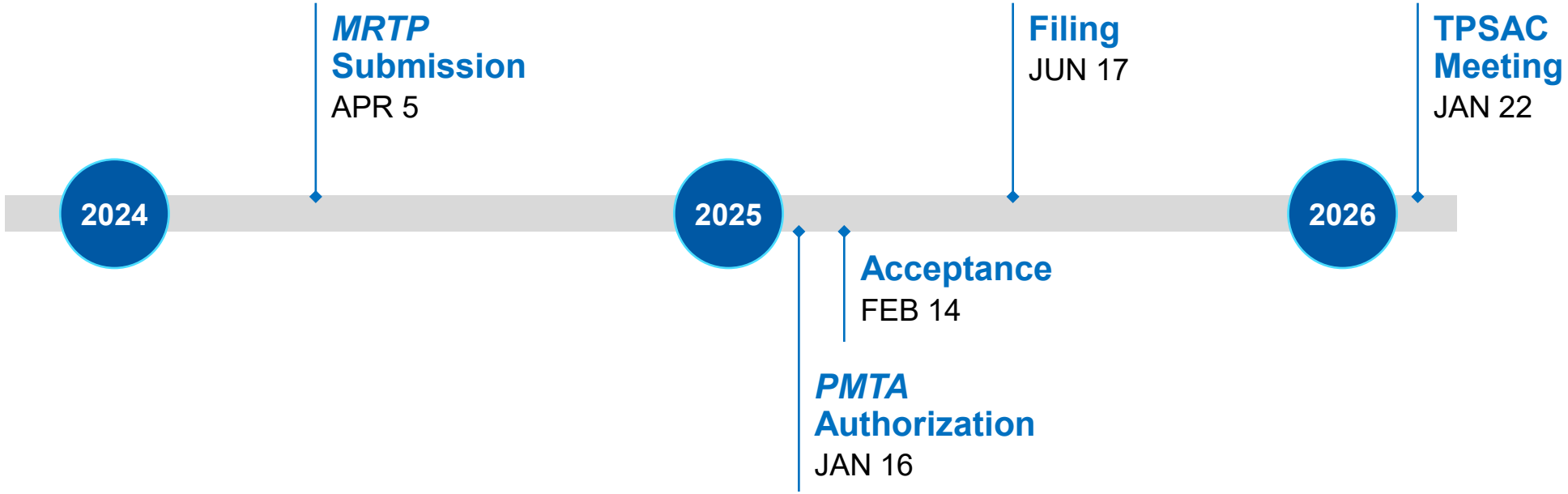
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ZYN – MRTP Application Timeline



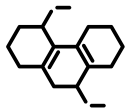
Using *ZYN* instead of cigarettes puts you at a lower risk of mouth cancer, heart disease, lung cancer, stroke, emphysema, and chronic bronchitis.

Clinical & Non-Clinical Scientific Assessment

Dr. Tryggve Ljung, MD, PhD
Global Medical Head of Oral Products

ZYN's Health Effects Can be Reasonably Predicted from Extensive Epidemiology on Snus Given Certain Conditions

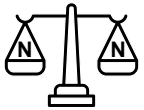
Long-term health effects of nicotine pouches can be reasonably predicted by drawing on data from snus, provided certain fundamental assumptions are satisfied:



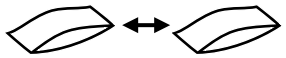
The same or less amount of harmful and potential harmful constituents



No new harmful or potentially harmful constituents present



The user is **not exposed to a higher level of nicotine**



Used in a similar way

Comparison of Product Characteristics









- Tobacco-based
- Placed in the upper lip
- Does not require spitting
- 8 mg nicotine/pouch
- 12-24 pouches/can

- Tobacco-leaf free
- Placed in the upper lip
- Does not require spitting
- 3 or 6 mg nicotine/pouch
- 15 pouches/can

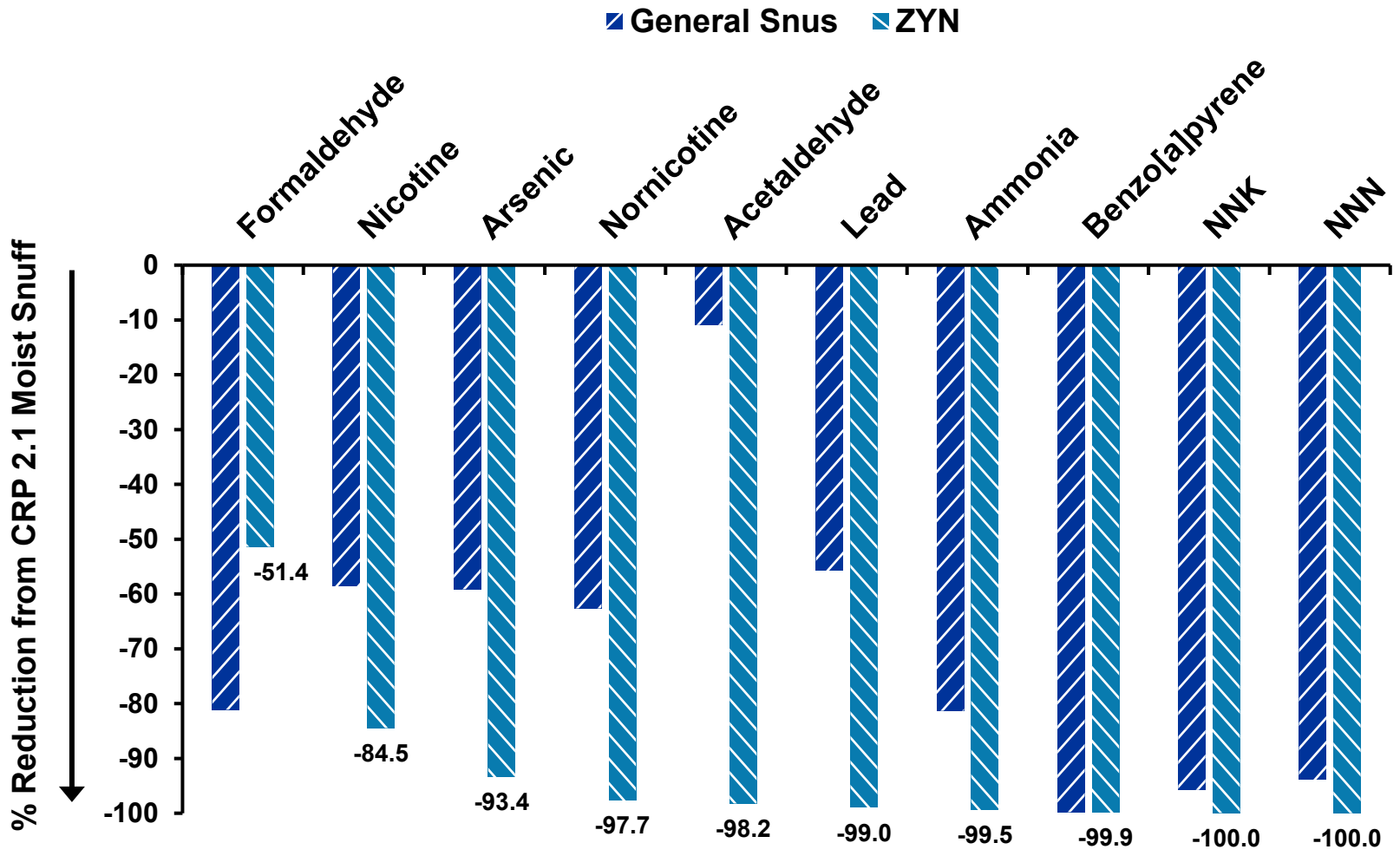
FDA's Prior Conclusions



"The chemistry review concluded that **comparisons between *General Snus* and [ZYN] are appropriate** given similarities in frequency of use (i.e, user topography), nicotine content, pH, and units of use."

– FDA ZYN PMTA TPL Review, Page 11 (2025)

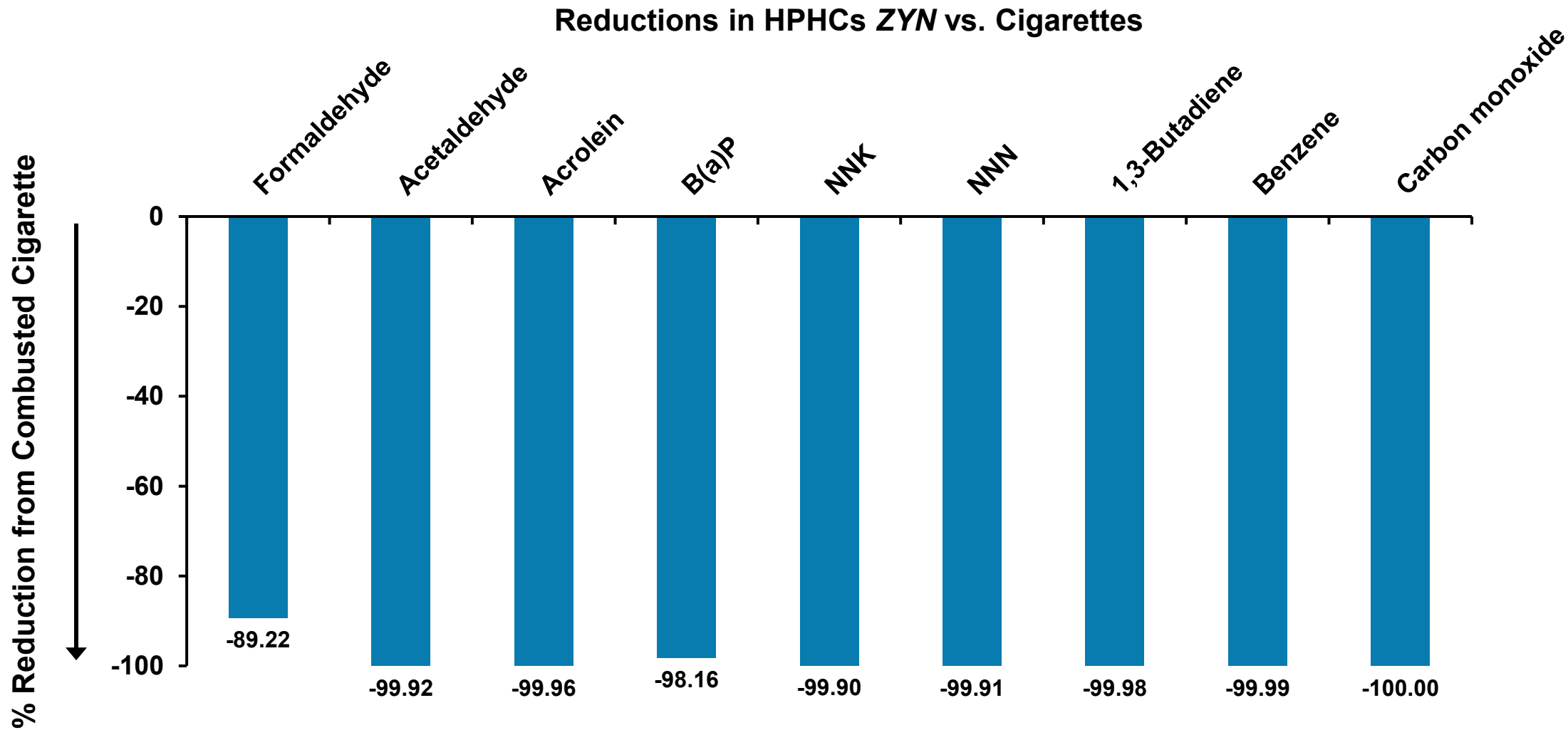
ZYN Nicotine Pouches Have Significantly Reduced Levels of Harmful Chemicals Compared to Reference Moist Snuff (CRP 2.1) and *General Snus*



"The test data demonstrates that the new products contain reliably lower levels of the majority of HPHCs, including nicotine, free nicotine, NNN, and NNK than Swedish Match General Snus products"

– FDA ZYN PMTA TPL Review, Page 15 (2025)

ZYN Nicotine Pouches Have Significantly Reduced Levels of Harmful Chemicals Compared to Cigarettes



Based on data on Swedish Match *ZYN* product and published smoke data, ISO and ISO-Intense, the average reduction of the 9 TobReg toxicants suggested by WHO, is 99 %

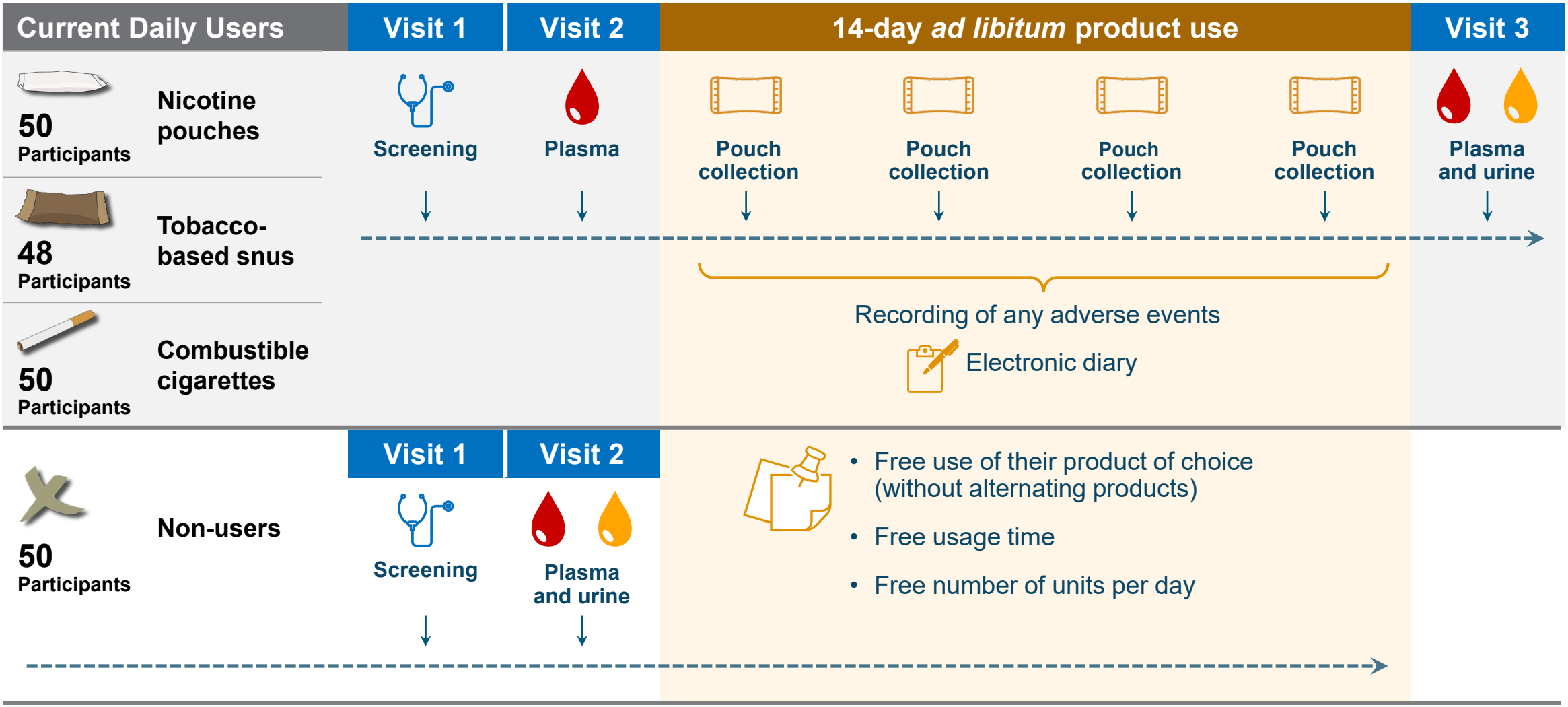
FDA's Prior Conclusions



"The toxicology review concludes that adults who smoke who switch completely to [ZYN] are expected to experience reduced risk of cancer, respiratory toxicity, and cardiovascular toxicity."

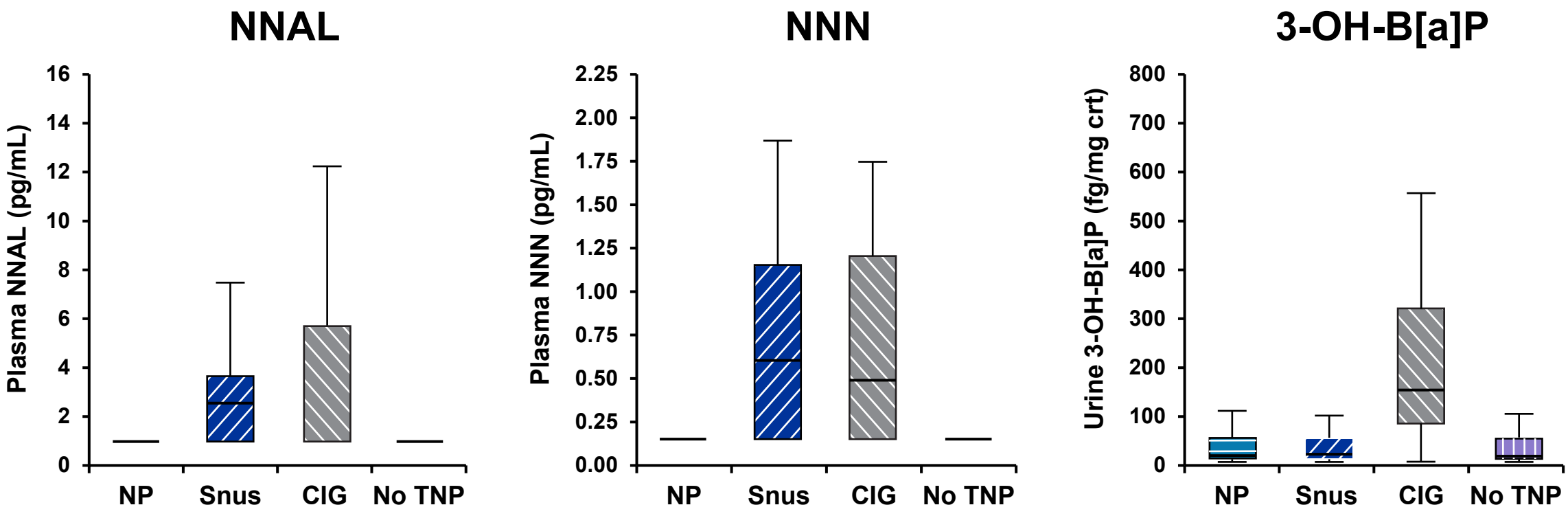
– FDA ZYN PMTA TPL Review, Page 6 (2025)

Biomarkers of Exposure (BoEs) – Study Design



Source: ISRCTN38557348 (SM22-03) Pramfalk et al., (in preparation)

Nicotine Pouch Users Have Reduced Biomarkers of Exposure (BoEs) for HPHCs

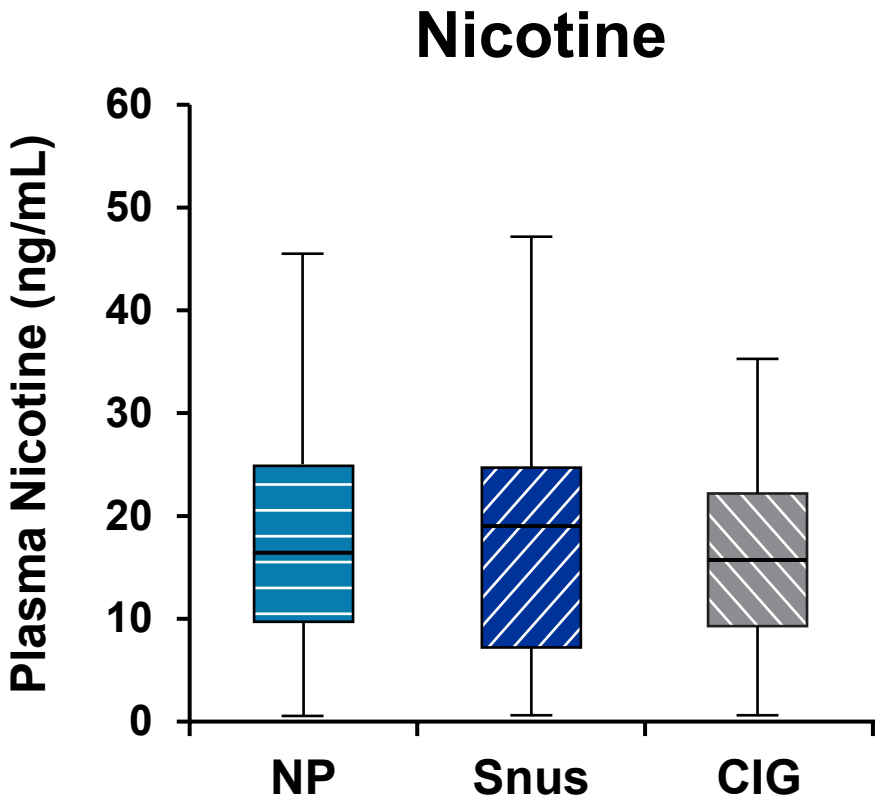


Plasma NNAL and NNN concentrations were similar between NP and non-users, and significantly lower compared to snus users and CIG users

Snus users and CIG users had similar plasma NNAL and NNN concentrations

NP=Nicotine pouch; CIG=Cigarettes; TNP=Tobacco and nicotine product.
Source: ISRCTN38557348 (SM22-03) Pramfalk et al., (in preparation)

Nicotine Pouch, Snus, & Cigarette Users Have Equivalent Plasma Levels of Nicotine BoEs



Plasma nicotine concentrations were similar in all user groups

Source: ISRCTN38557348 (SM22-03) Pramfalk et al., (in preparation)

FDA's Prior Conclusions

"Based on the information provided in the PMTAs, the **abuse liability of [ZYN] is lower than combusted cigarettes and is similar to smokeless tobacco products.**"

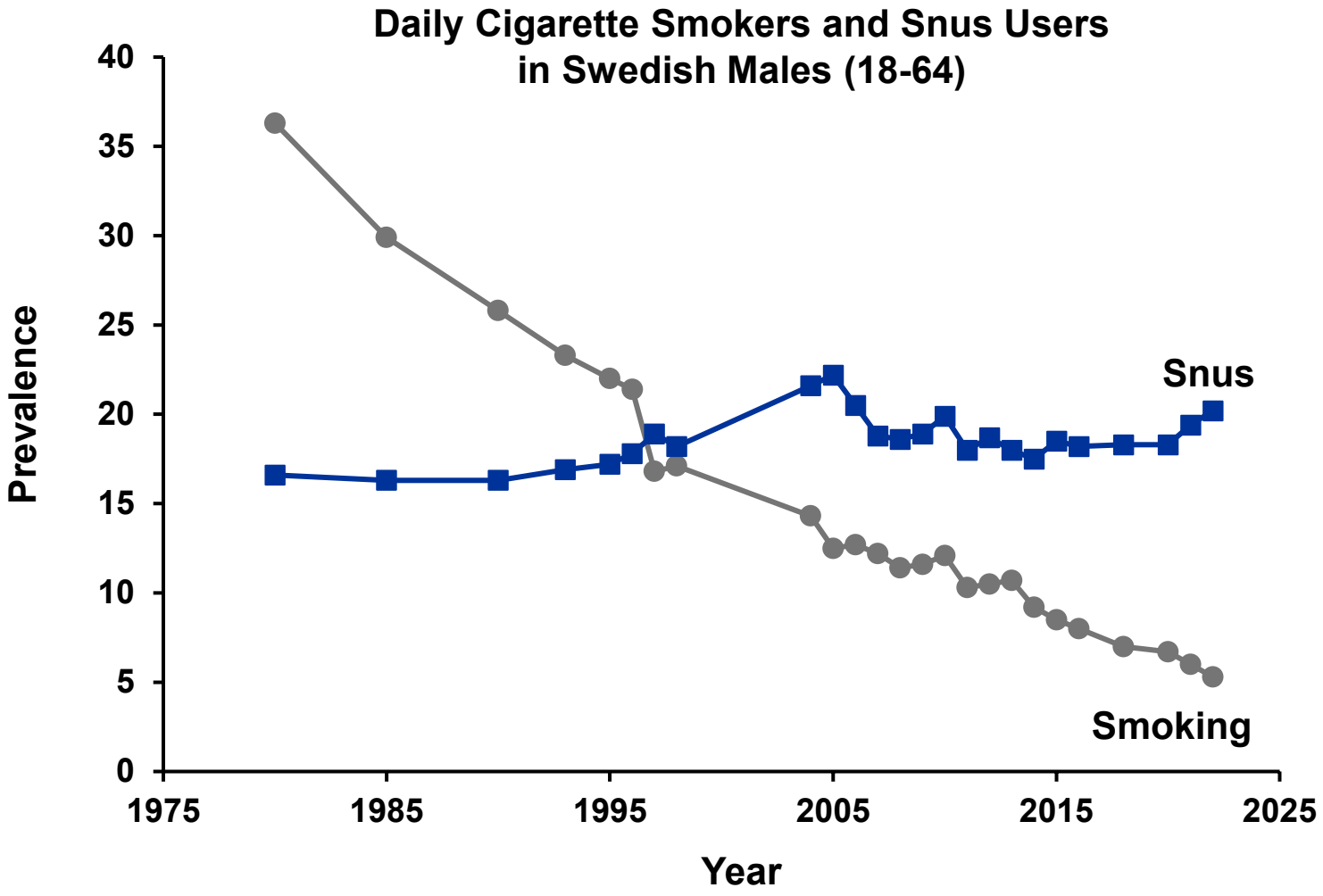
– FDA ZYN PMTA TPL Review, Page 56 (2025)

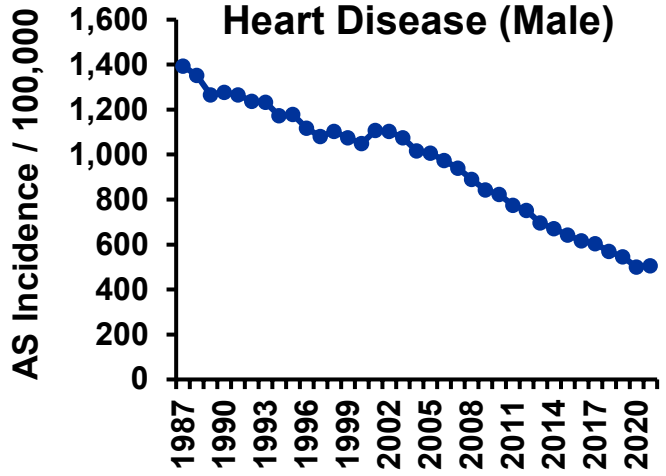
FDA's Prior Conclusions

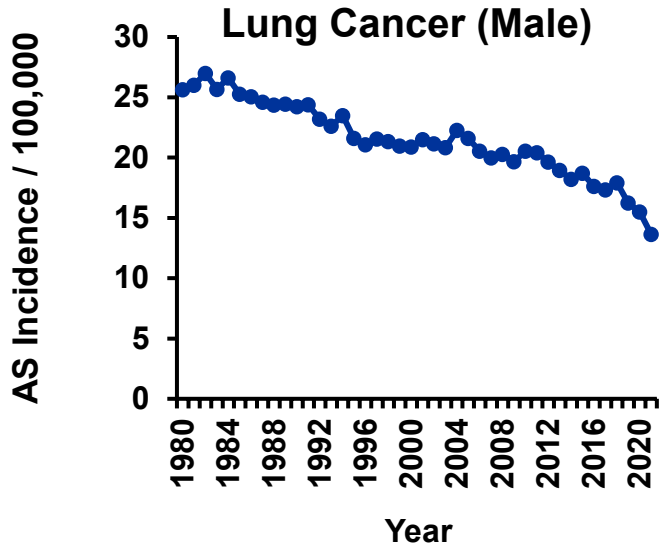
"The epidemiology review concluded that the applicant's justification for **bridging the published literature on the long-term health effects of Swedish snus to the new products based on similarities in user topography was reasonable.**"

– FDA ZYN PMTA TPL Review, Page 51 (2025)

The Swedish Experience – Epidemiology

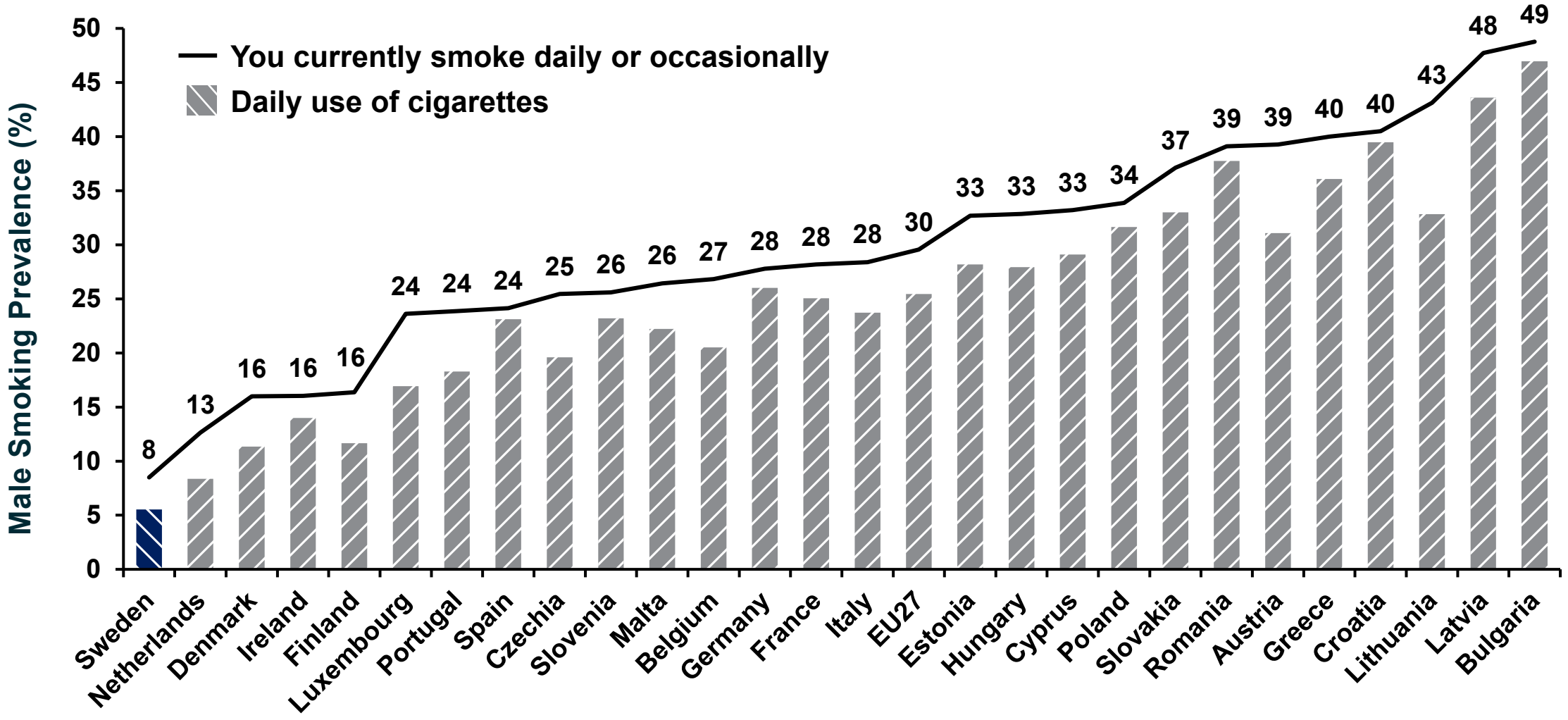






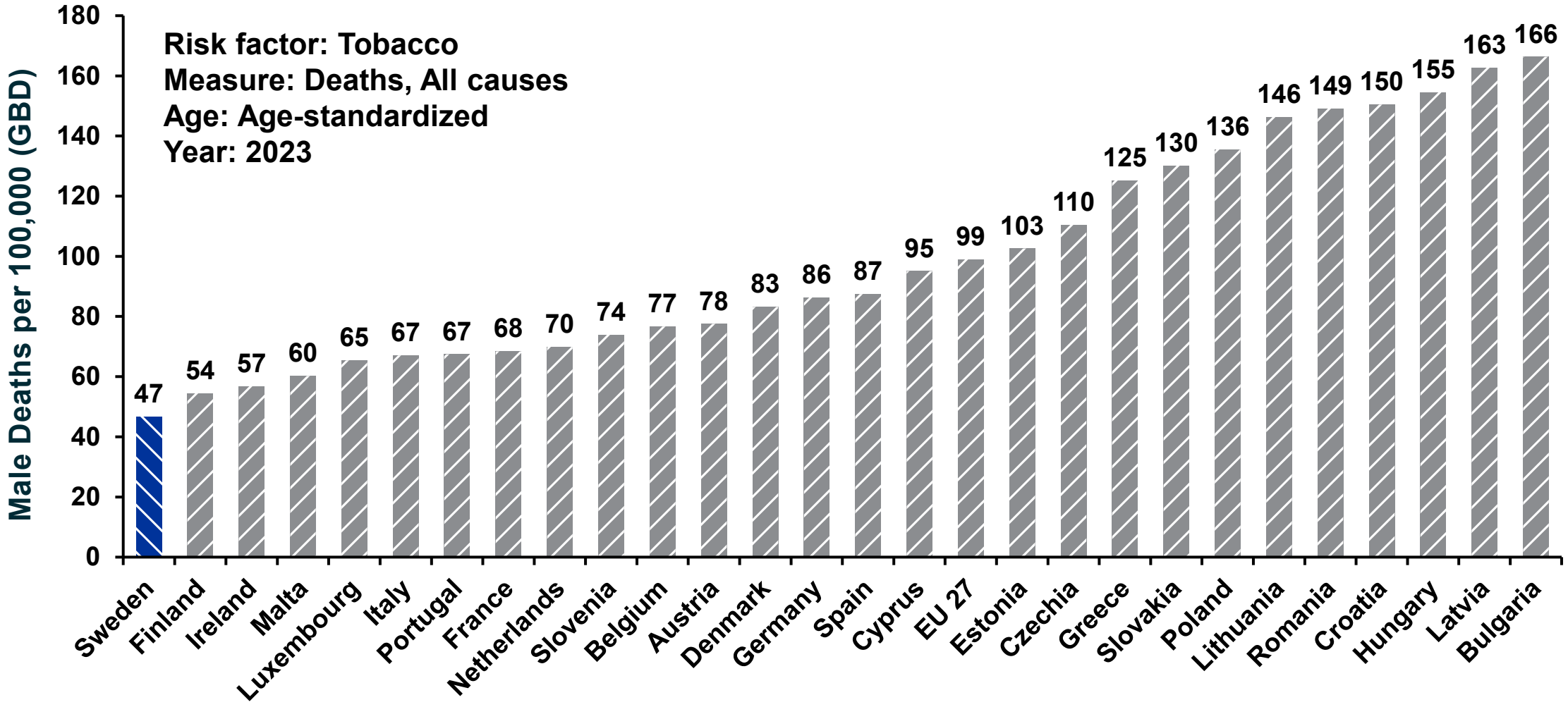
Source: Incidence Data - Swedish National Board Of Health And Welfare, Statistical Database (Accessed 5/2023); Prevalence Data: 1980-1998 - Henningfield J, Fagerstrom K Tobacco Control 2001;10:253-257; 2004-2022 – National Public Health Survey/Living Habits/ Tobacco And Nicotine (Accessed 6/2023)

The Swedish Experience – Prevalence



Dataset Special Eurobarometer 539: Attitudes of Europeans towards tobacco and related products, June 2024,

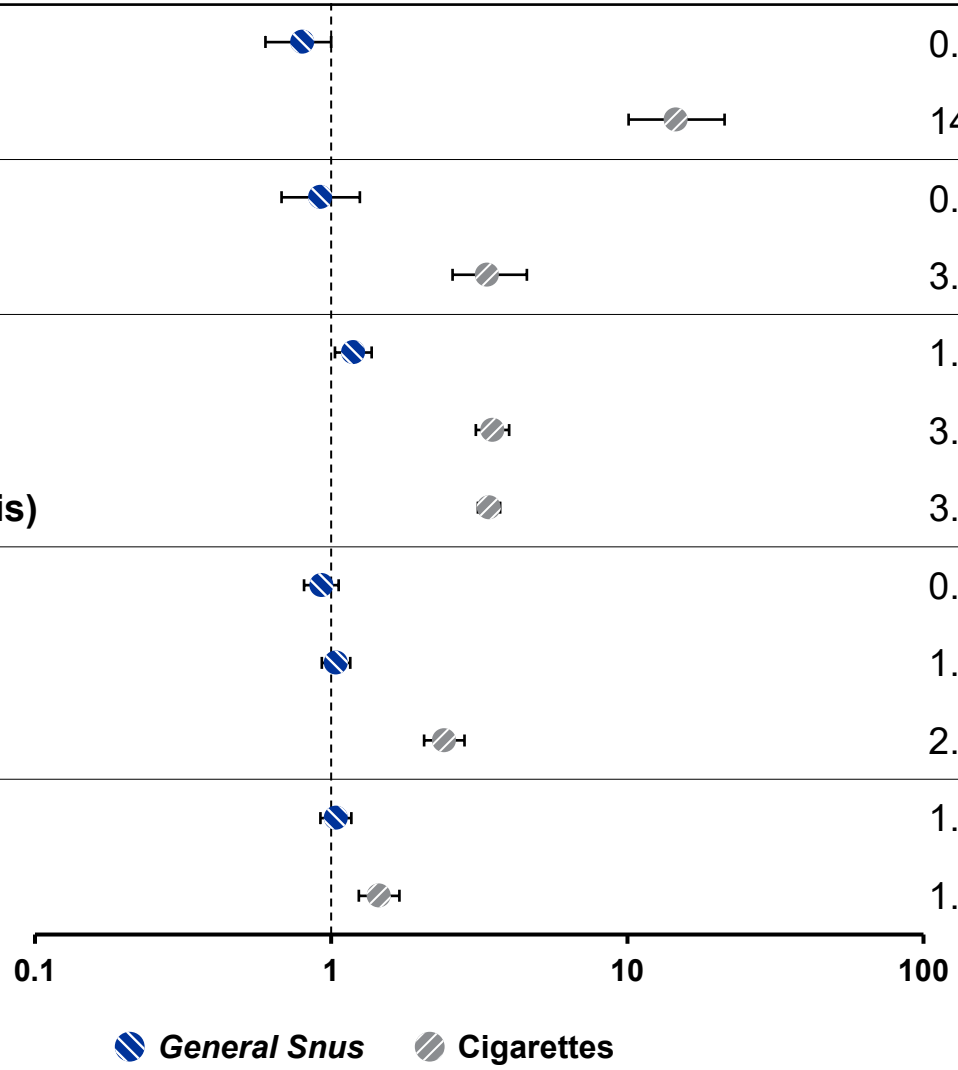
The Swedish Experience – Mortality



Global Burden of Disease Collaborative Network. Global Burden of Disease Study 2023 (GBD 2023) Results. Seattle, United States: Institute for Health Metrics and Evaluation (IHME), 2024. Available from https://vizhub.healthdata.org/gbd-results/.

Using *General Snus* instead of cigarettes puts you at a lower risk of mouth cancer, heart disease, lung cancer, stroke, emphysema, and chronic bronchitis.

		Risk Estimate (95% CI)
Lung Cancer	Boffetta et al. 2008	0.80 (0.60-1.00)
	O'Keeffe et al., 2018	14.6 (10.1-21.3)
Mouth Cancer	Siddiqi, 2020	0.92 (0.68-1.25)
	Ansary-Moghaddam, 2009	3.36 (2.57-4.58)
Emphysema & Chronic Bronchitis	Gudnadottir et al., 2017	1.19 (1.03-1.37)
	Forey et al., 2011 (Emphysema)	3.51 (3.08-3.99)
	Forey et al., 2011 (Chronic Bronchitis)	3.41 (3.13-3.72)
Heart Disease	Gupta et al., 2019 (CVD)	0.93 (0.81-1.06)
	Rostron et al., 2018 (IHD)	1.04 (0.93-1.16)
	Hacksaw et al., 2018	2.41 (2.06-2.82)
Stroke	Roston et al., 2018	1.04 (0.92-1.17)
	Luo et al., 2022	1.45 (1.24-1.70)



Dark blue points represent snus data; Gray points represent cigarette data.
CVD=Cardiovascular Disease; IHD=Ischemic Heart Disease
Relative risk is used where Hazard Ratios were not available.

FDA's Prior Conclusions

"The applicant reasoned that since **the new products have similar user topography but lower HPHCs levels compared to Swedish snus, the health effects of Swedish snus represent an upper limit on the likely long-term health effects of the new products**. The medical, epidemiology, and toxicology reviews of these PMTAs found the applicant's rationale reasonable and, as TPL, I concur."

– FDA ZYN PMTA TPL Review, Page 51 (2025)

Conclusion

- **Epidemiological evidence** demonstrates that Swedish snus carries a significantly lower risk of cancer, cardiovascular disease, and respiratory disease compared to cigarette smoking
- **Chemistry and toxicology studies** show that *ZYN* has an even lower risk profile than *General Snus* and far below that of cigarettes
- **Pharmacological evaluation** found that *ZYN*'s abuse liability is lower than cigarettes and comparable to other smokeless tobacco products such as *General Snus*

FDA concluded that "the health effects of Swedish snus represent an upper limit on the likely long-term health effects of [ZYN]."[1]

1. FDA *ZYN* PMTA TPL Review, Page 24 (2025)

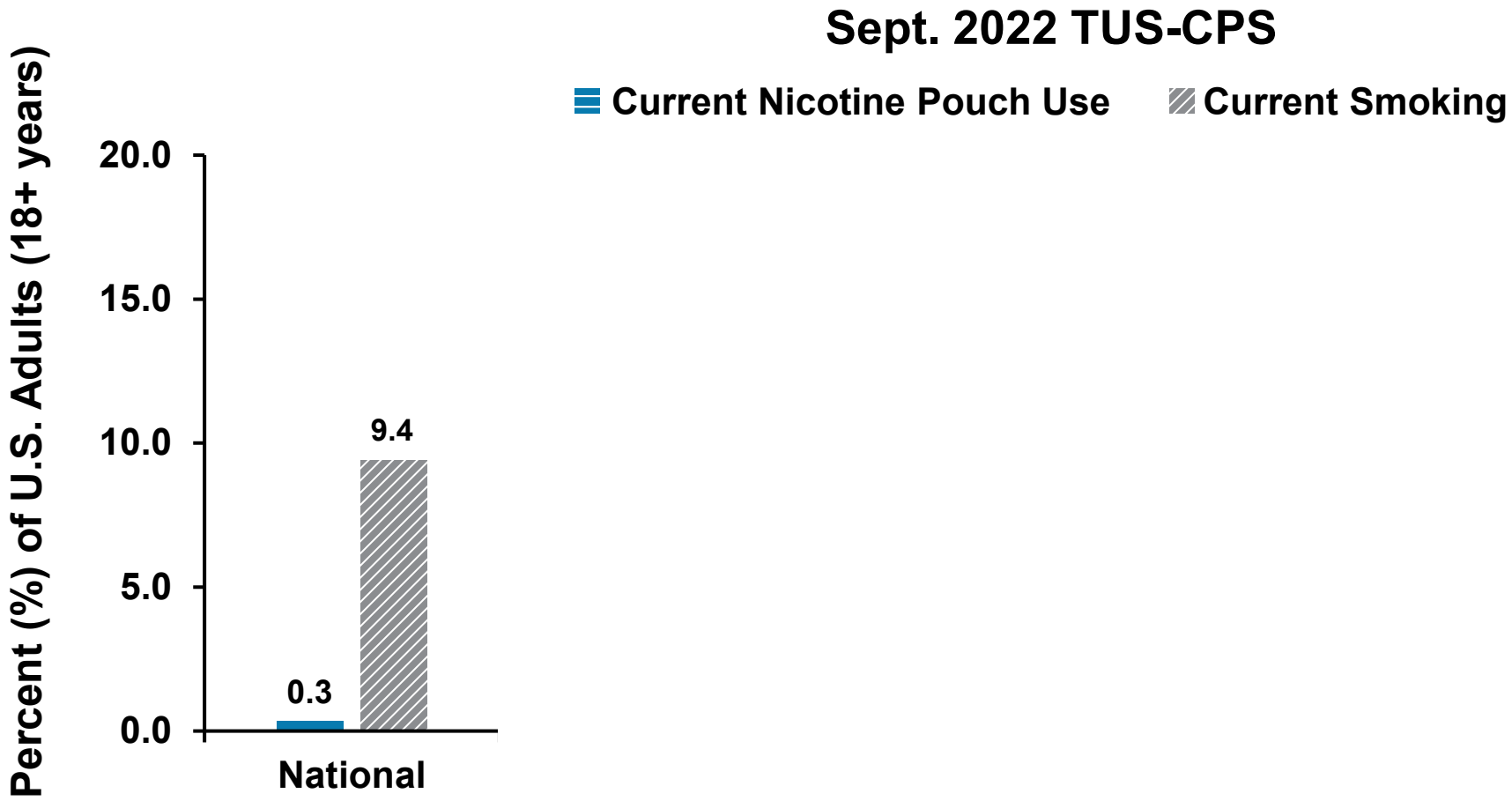
Consumer Understanding, Perceptions, & Behavior

Dr. Jessica Seifert, PhD, MPH
Head of Regulatory Insights, U.S.

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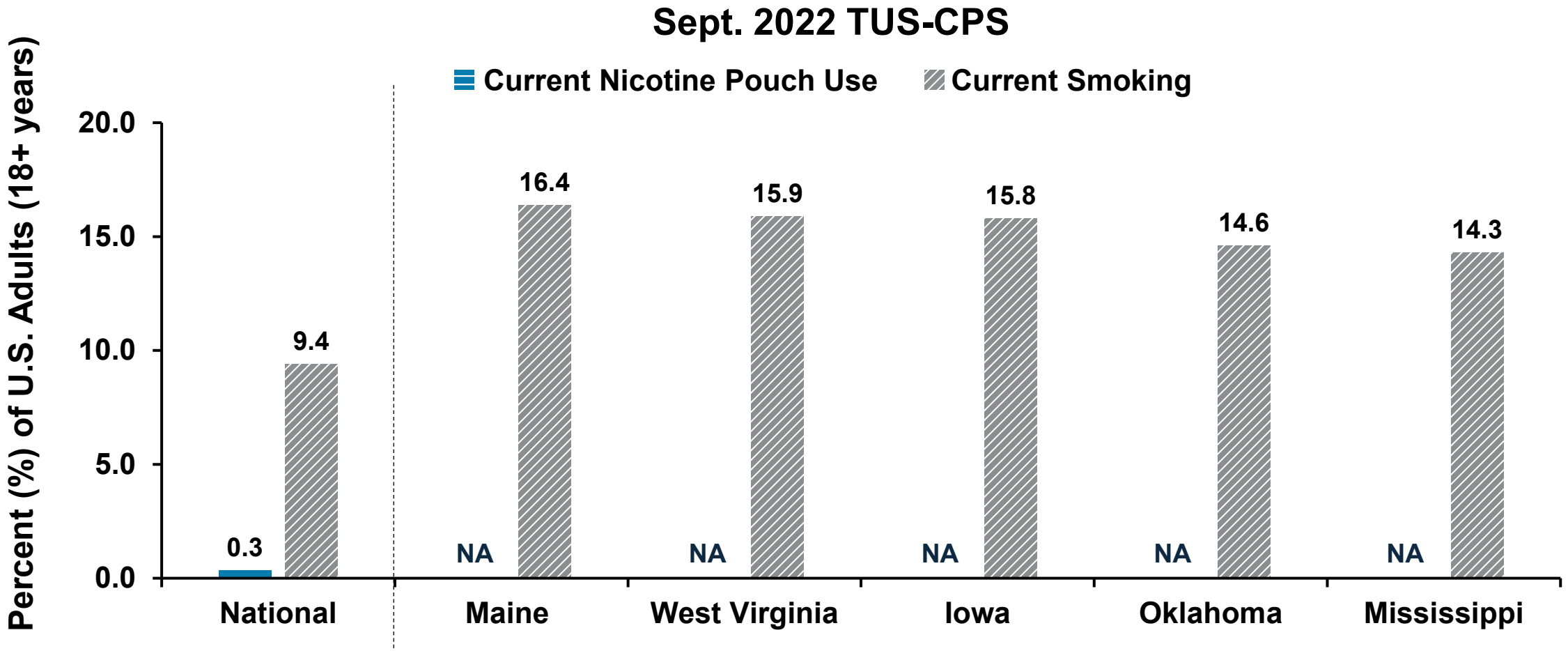
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3. *ZYN* Users Switch From or Reduce Cigarette Use
4. Proposed Claim Does Not Increase Appeal to Nonusers

Cigarette Smoking among U.S. Adults Remains High



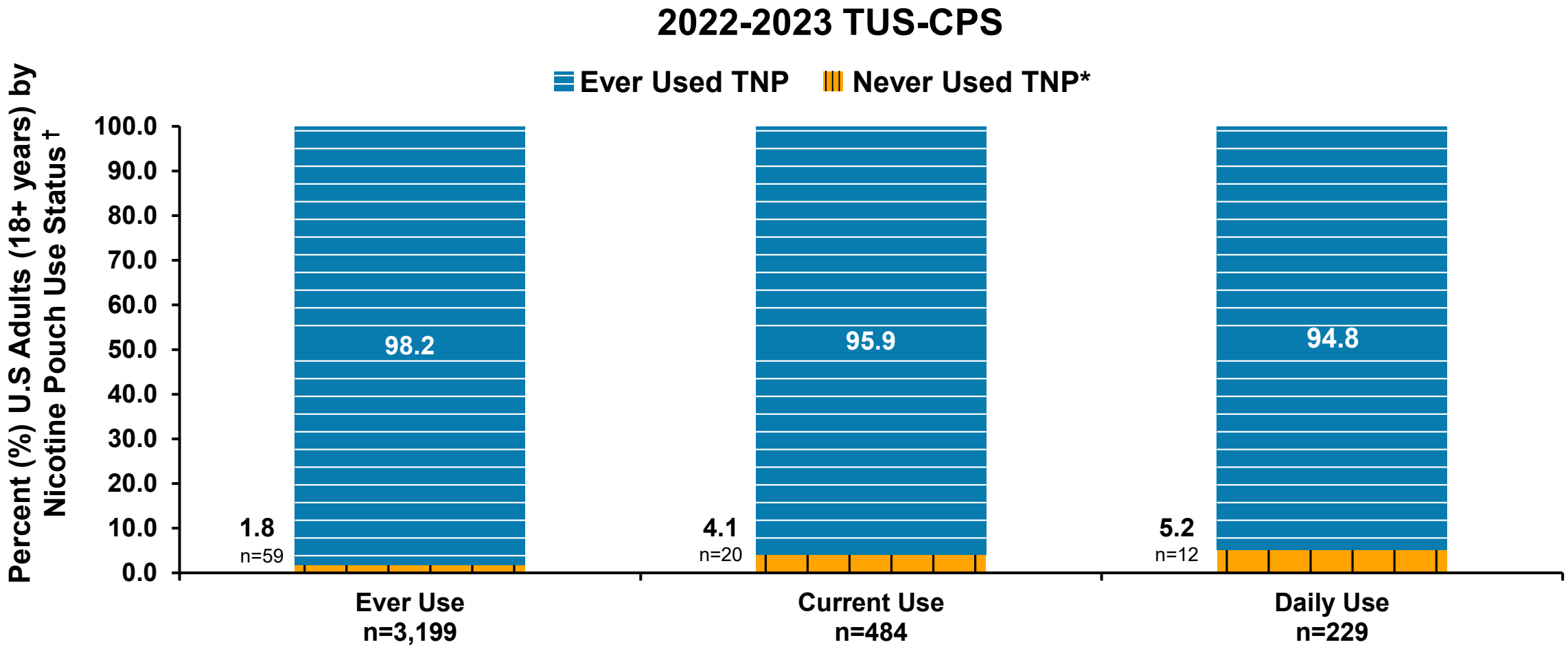
Current Smoking defined as having smoked ≥100 cigarettes & reporting smoking "Every day" or "Some days".
Current Nicotine Pouch Use defined as reporting using nicotine pouches "Daily" or "Some days".
Source: 2022 CPS-TUS; Delnevo CD, et al. (2025). (2022-2023). *JAMA Network Open, 8*(9), e2531155. https://doi.org/10.1001/jamanetworkopen.2025.31155
Stone MD et al. (2025). *JAMA Network Open, 8*(4), e256834. https://jamanetwork.com/journals/jamanetworkopen/fullarticle/2833289

Cigarette Smoking among U.S. Adults Remains High



NA = Not Available.
Current Smoking defined as having smoked ≥100 cigarettes & reporting smoking "Every day" or "Some days".
Current Nicotine Pouch Use defined as reporting using nicotine pouches "Daily" or "Some days".
Source: 2022 CPS-TUS; Delnevo CD, et al. (2025). (2022-2023). *JAMA Network Open, 8*(9), e2531155. https://doi.org/10.1001/jamanetworkopen.2025.31155
Stone MD et al. (2025). *JAMA Network Open, 8*(4), e256834. https://jamanetwork.com/journals/jamanetworkopen/fullarticle/2833289

Nicotine Pouch Use Was "Virtually Non-Existent for Tobacco-Naïve Adults"



TNP=Tobacco nicotine products
*Estimates may not be reliable for "Daily Use" of nicotine pouches, and caution should be used when interpreting.
†Unweighted counts and percentages.
Naïve tobacco users defined as responding "No" to ever using cigarettes, e-cigarettes, cigars, smokeless tobacco, hookah, pipe, or heated tobacco
Source: 2022-2023 TUS-CPS. Delnevo CD, Tomaino M, Hrywna M, Bover Manderski MT. (2025). Patterns of nicotine pouch use among adults in the U.S., 2022-2023. *JAMA Network Open, 8*(9), e2531155. https://doi.org/10.1001/jamanetworkopen.2025.31155

ZYN User Profile Study – Study Design

Recruitment of *ZYN* Users

- ≥21 years old
- Registered in database + Opted in to receive communication
- Used *ZYN* at least once a week in the past 30-days

DEC 2020

LAUNCH

SCREENER

15 DEC 2020

First Participant Enrolled

20 MAR 2021

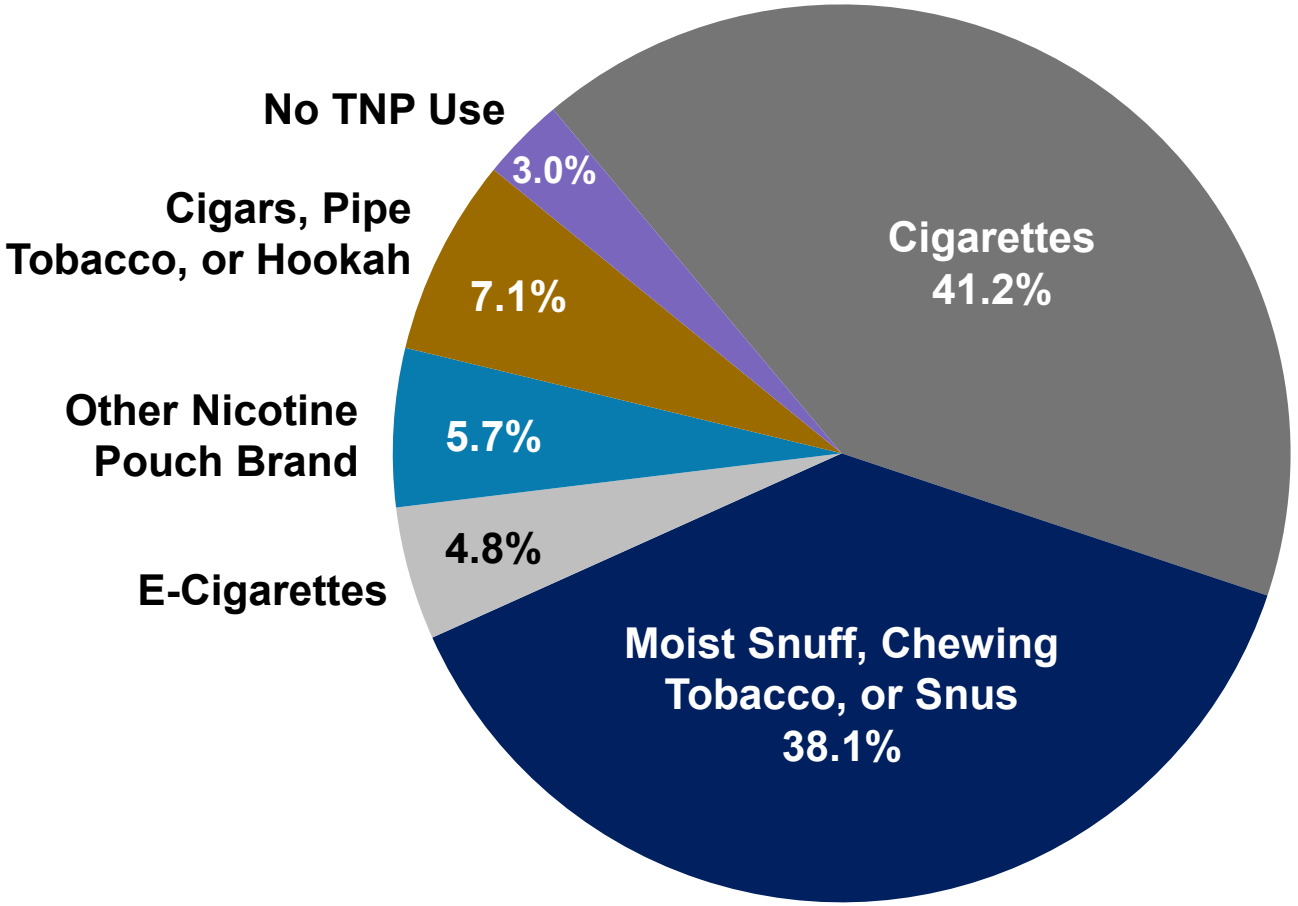
Last Participant Enrolled

Source: SMNA 20-003. *ZYN* User Profile Study Report. N=1,305

97% of *ZYN* Users Have a Previous History of TNP Use

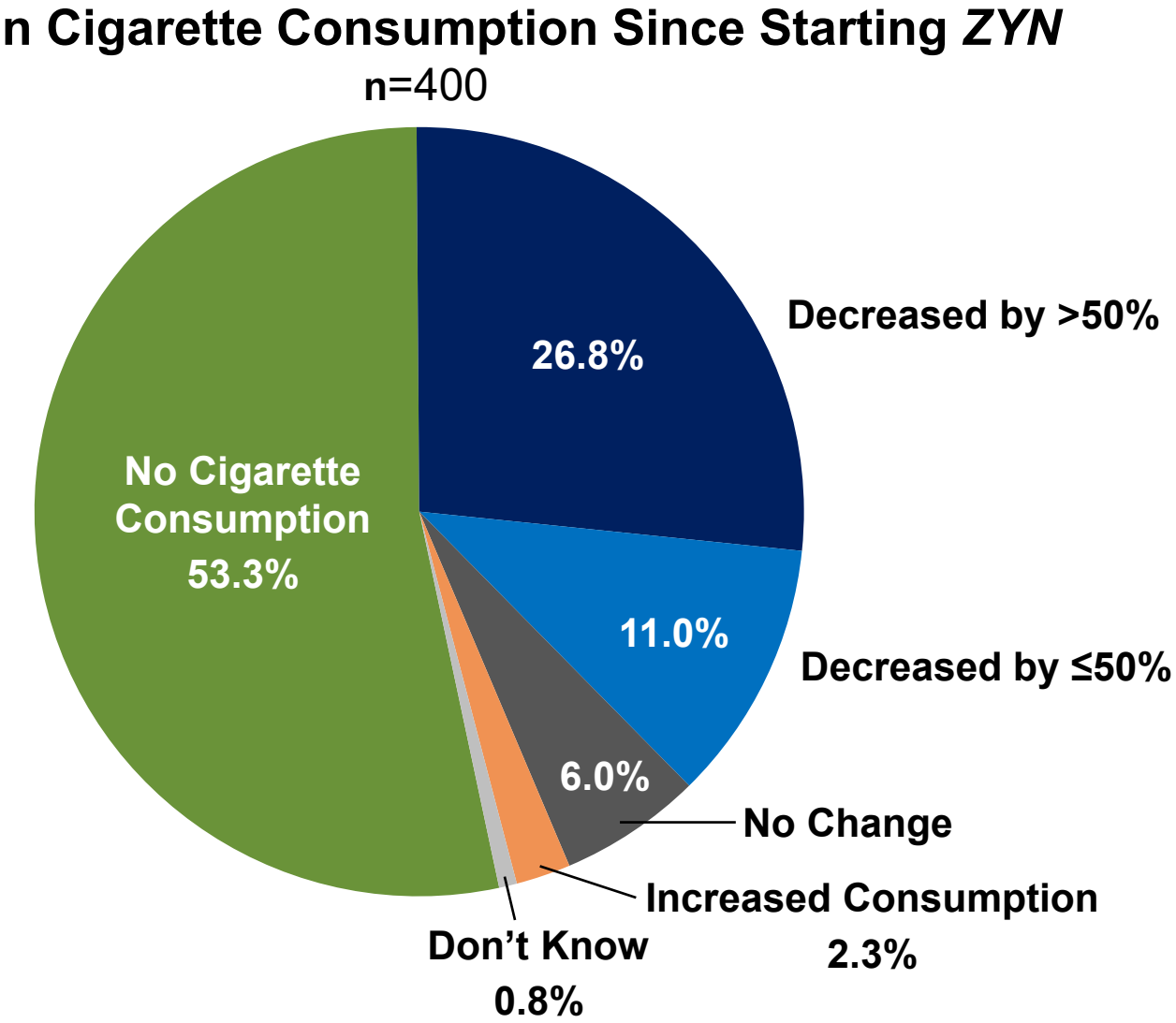
First Type of Tobacco or Nicotine Product Used Prior to *ZYN* Use

N=1,305



Source: SMNA 20-003. *ZYN* User Profile Study Report. 2021. Report Table 19.

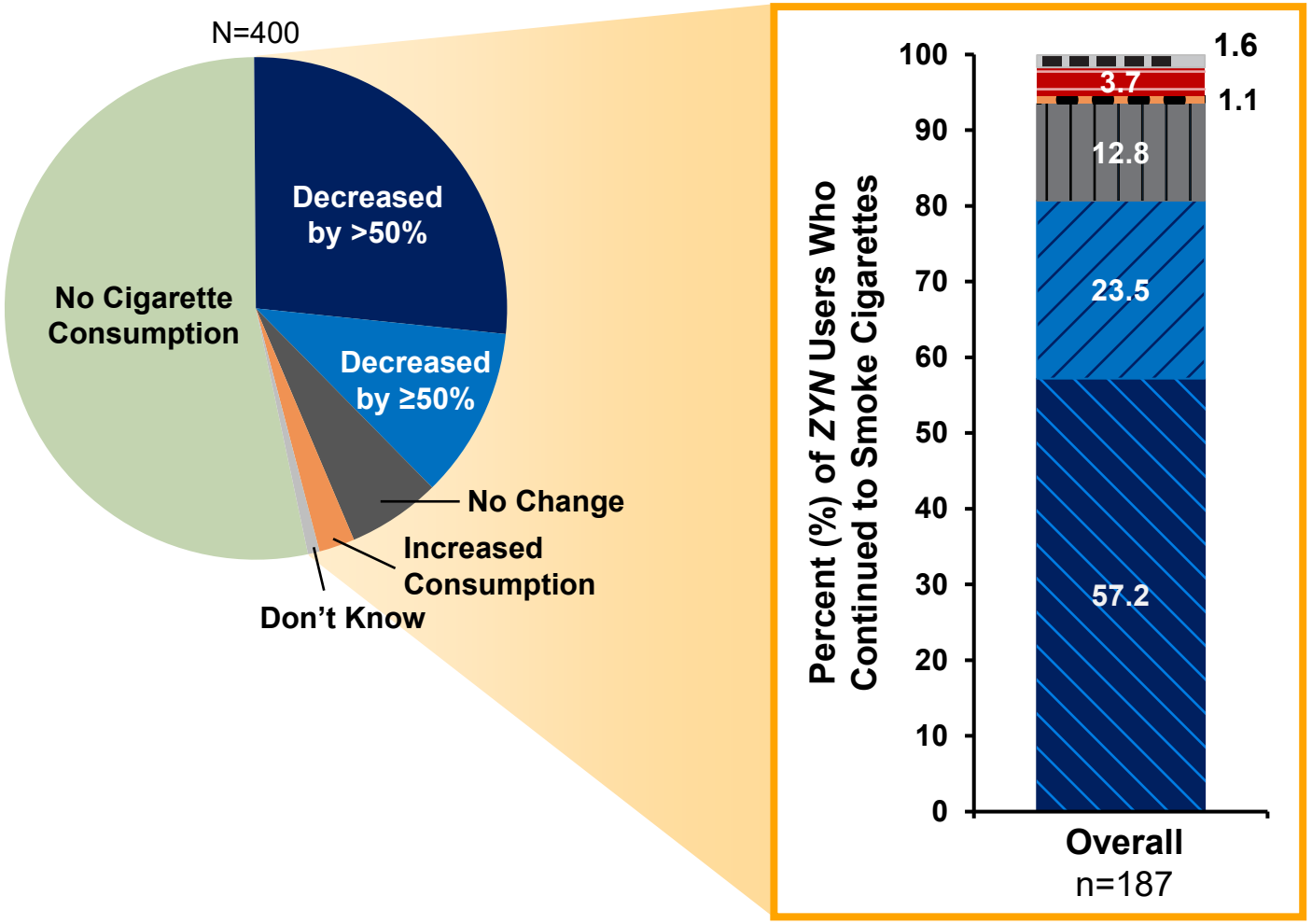
Most *ZYN* Users Stop Smoking



Source: SMNA 20-003. *ZYN* User Profile Study Report – Post-Hoc Addendum. 2021. Report Table 24a.

Most *ZYN* Users who Continue to Smoke Reduce Their Cigarette Consumption After Starting *ZYN*

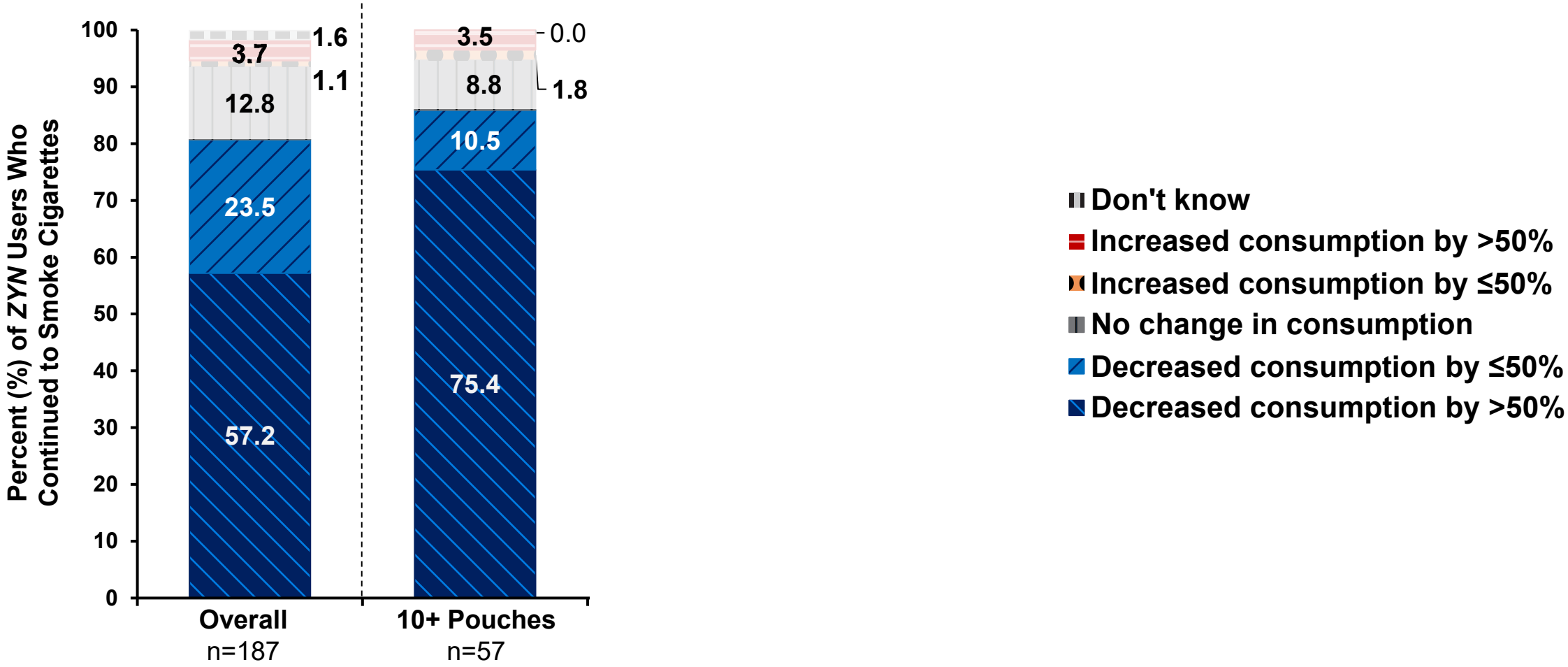
Change in Cigarette Consumption Since Starting *ZYN*
Among Those Who Continued to Smoke By Daily *ZYN* Use Intensity



Source: SMNA 20-003. *ZYN* User Profile Study Report. 2021. Report Table 45.

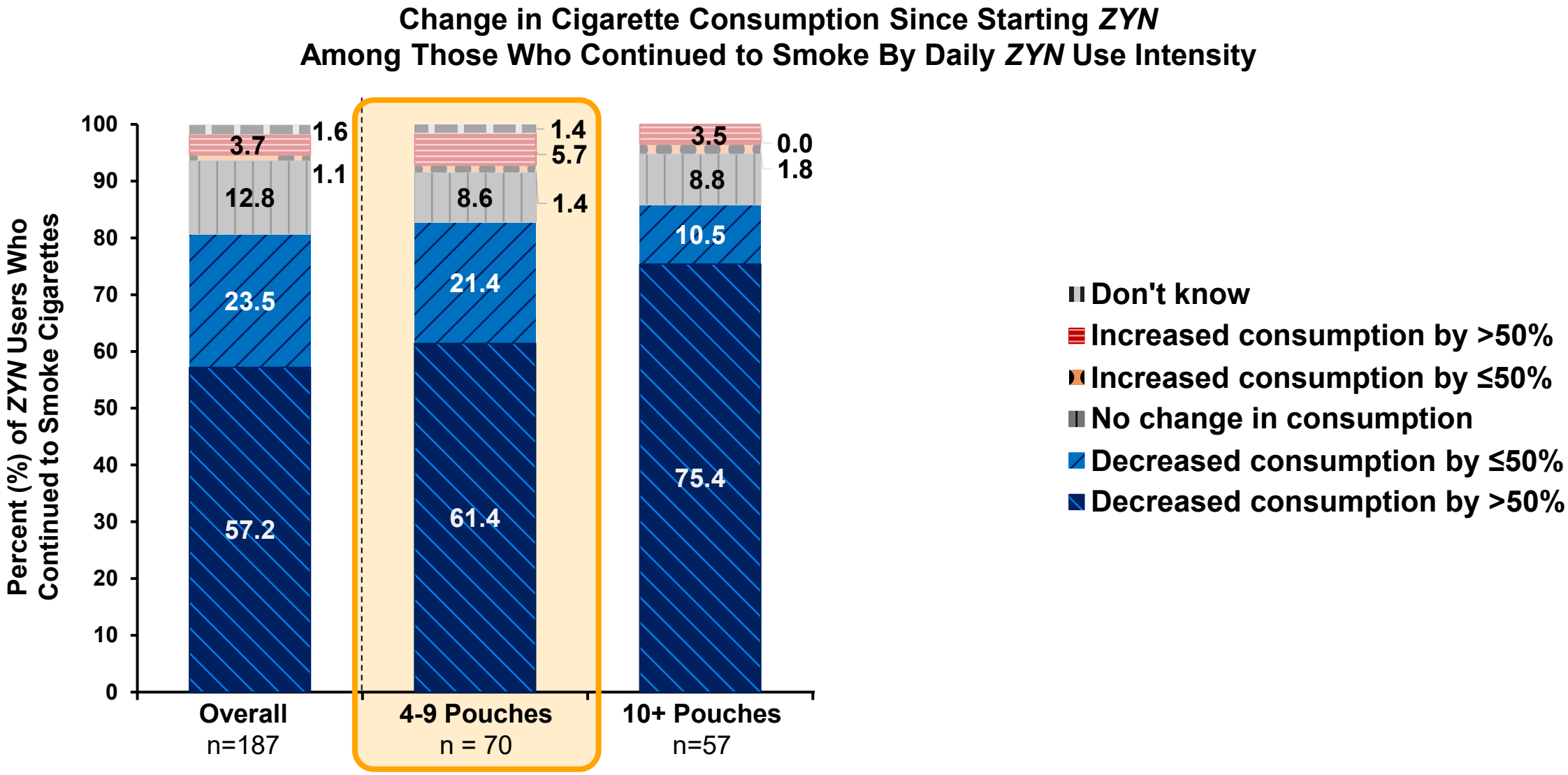
Higher Daily *ZYN* Use Associated with Greater Decreases in Cigarette Consumption

Change in Cigarette Consumption Since Starting *ZYN*
Among Those Who Continued to Smoke By Daily *ZYN* Use Intensity



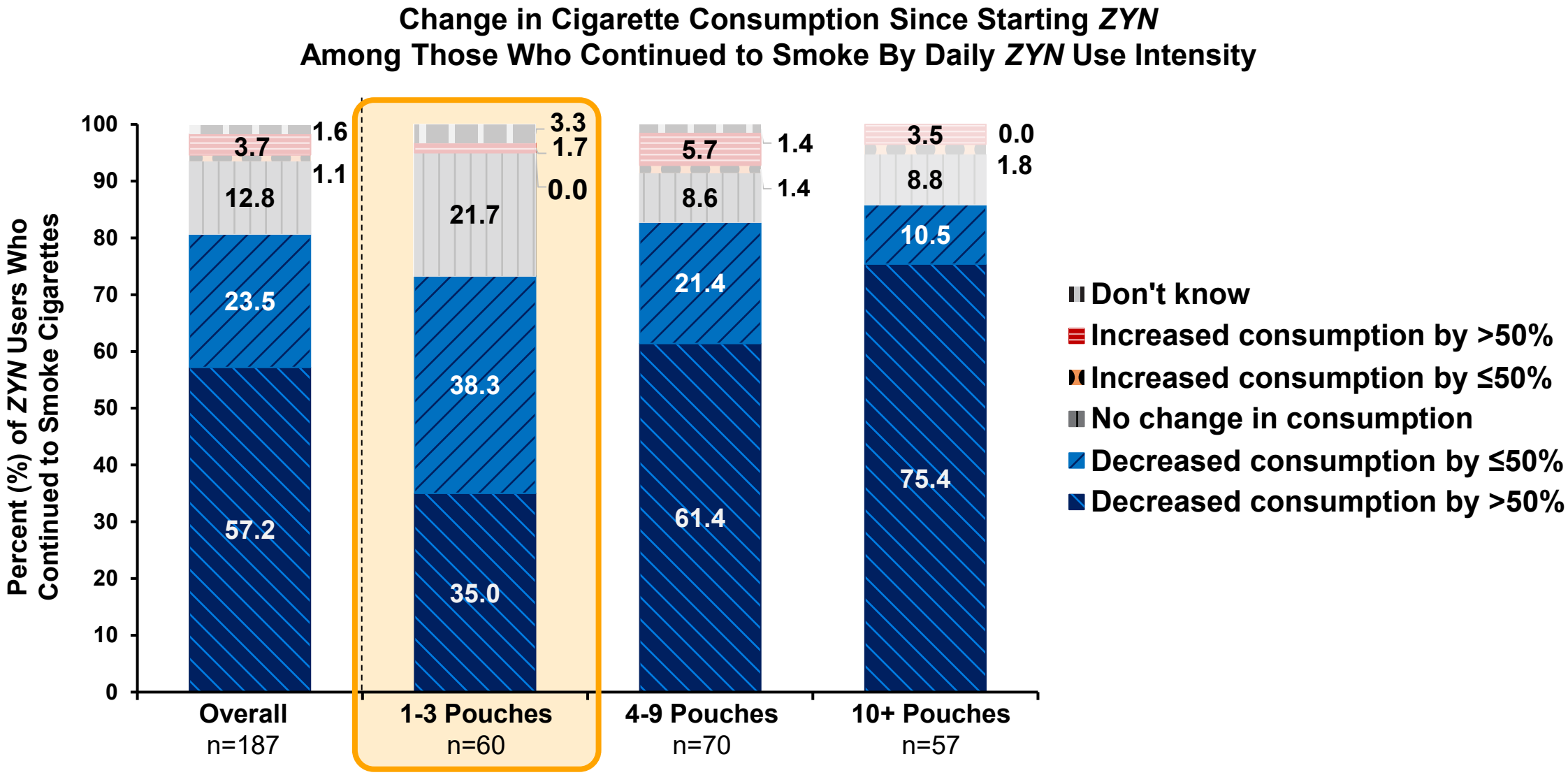
Source: SMNA 20-003. *ZYN* User Profile Study Report. 2021. Report Table 45.

Higher Daily *ZYN* Use Associated with Greater Decreases in Cigarette Consumption



Source: SMNA 20-003. *ZYN* User Profile Study Report. 2021. Report Table 45.

Higher Daily *ZYN* Use Associated with Greater Decreases in Cigarette Consumption



Source: SMNA 20-003. *ZYN* User Profile Study Report. 2021. Report Table 45.

Consumers Understand the Need to Completely Switch

Revisiting General Snus



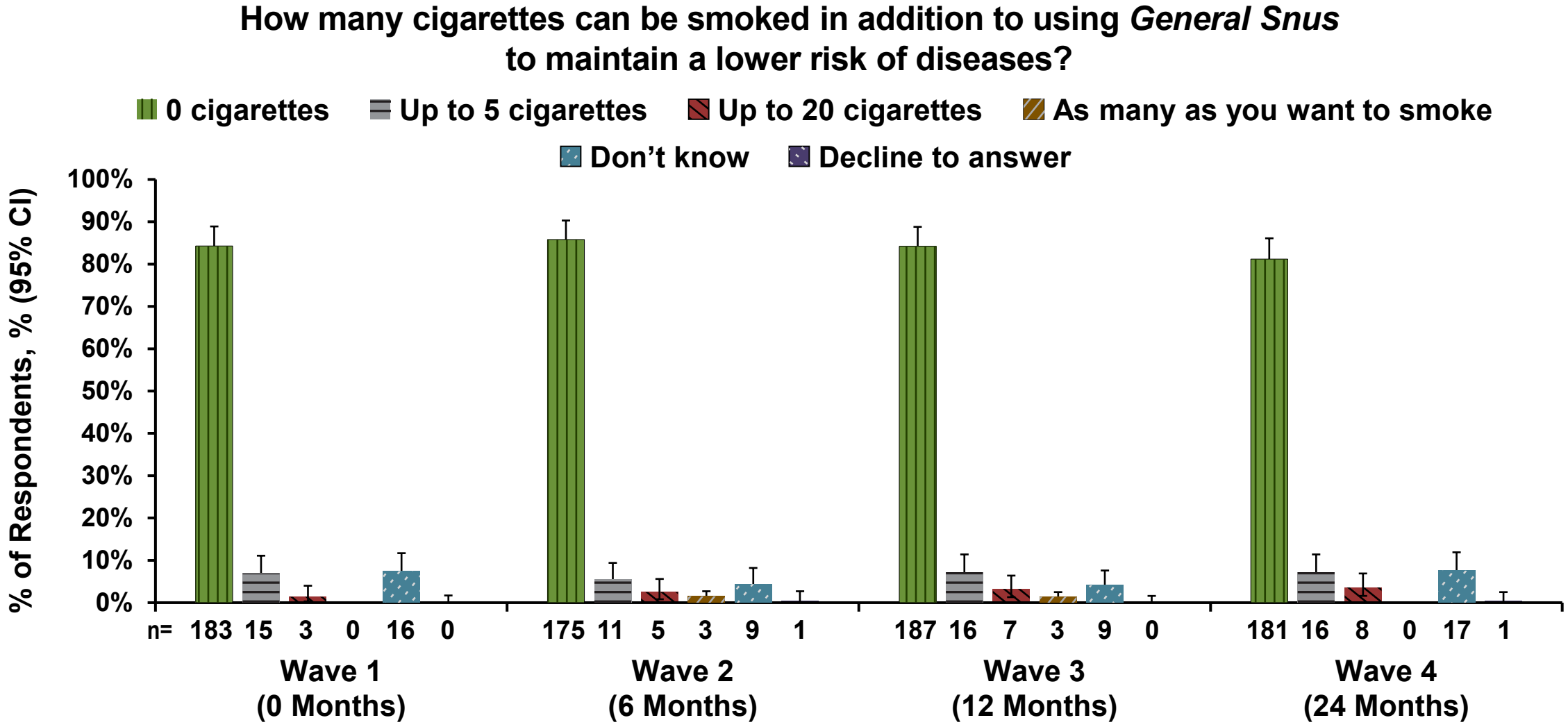
"[T]he proposed claim **did *not* lead smokers to believe** that partial substitution would reduce their disease risk."

– FDA GENERAL SNUS MRTPA TPL Review, Page 37 (2019)

"[T]he proposed claim **enabled consumers to understand** that dual use of *General Snus* with cigarettes is more harmful than exclusively using *General Snus*."

– FDA GENERAL SNUS MRTPA TPL Review, Page 34 (2019)

Respondents Overwhelmingly Understand Need to Completely Switch to Maintain a Lower Risk of Disease



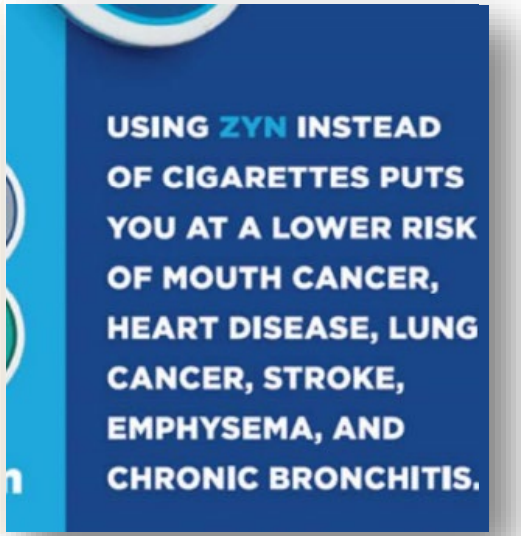
Source: *General Snus* POU Study. This analysis was conducted using data from the 281 participants who completed all four waves. The question was asked of only those respondents who correctly identified that using *General Snus* instead of cigarettes puts you at a lower risk of disease. Question: "You said that using *General Snus* instead of cigarettes puts you at lower risk of diseases. If you are going to use *General Snus* instead of cigarettes to lower your risk of diseases, how many cigarettes, if any, can you smoke per day?"

ZYN Perceptions and Likelihood of Use Study – Study Design

Control: No Claim



Test: With Claim

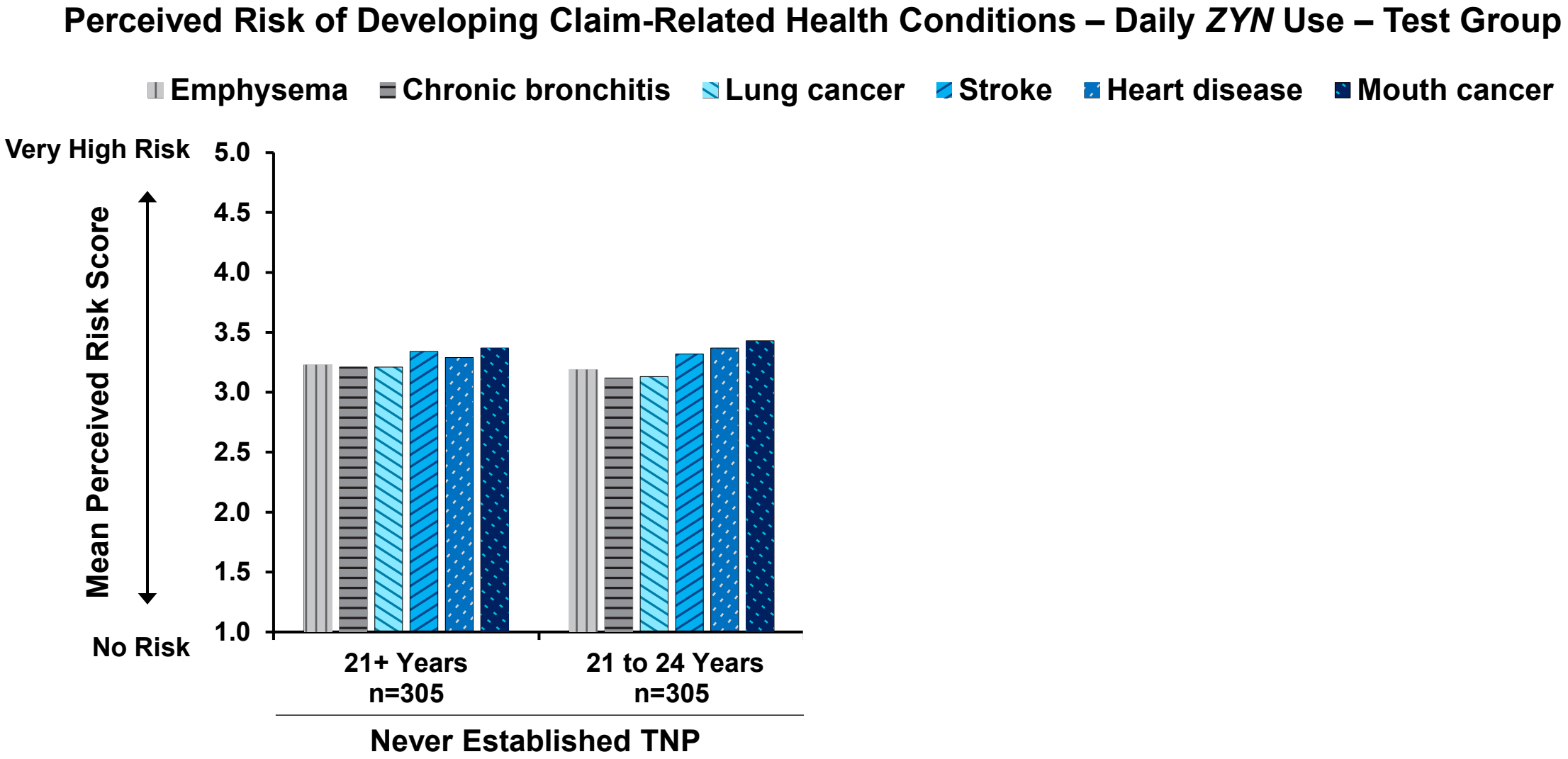


Recruitment

Study Groups	Total n
Current Smokers	1,010
Former Smokers / Other TNP users	610
Current Smokeless Users	610
Never TNP Users	610
Never TNP Users (oversample 21-24)	610
TOTAL	**3,450**

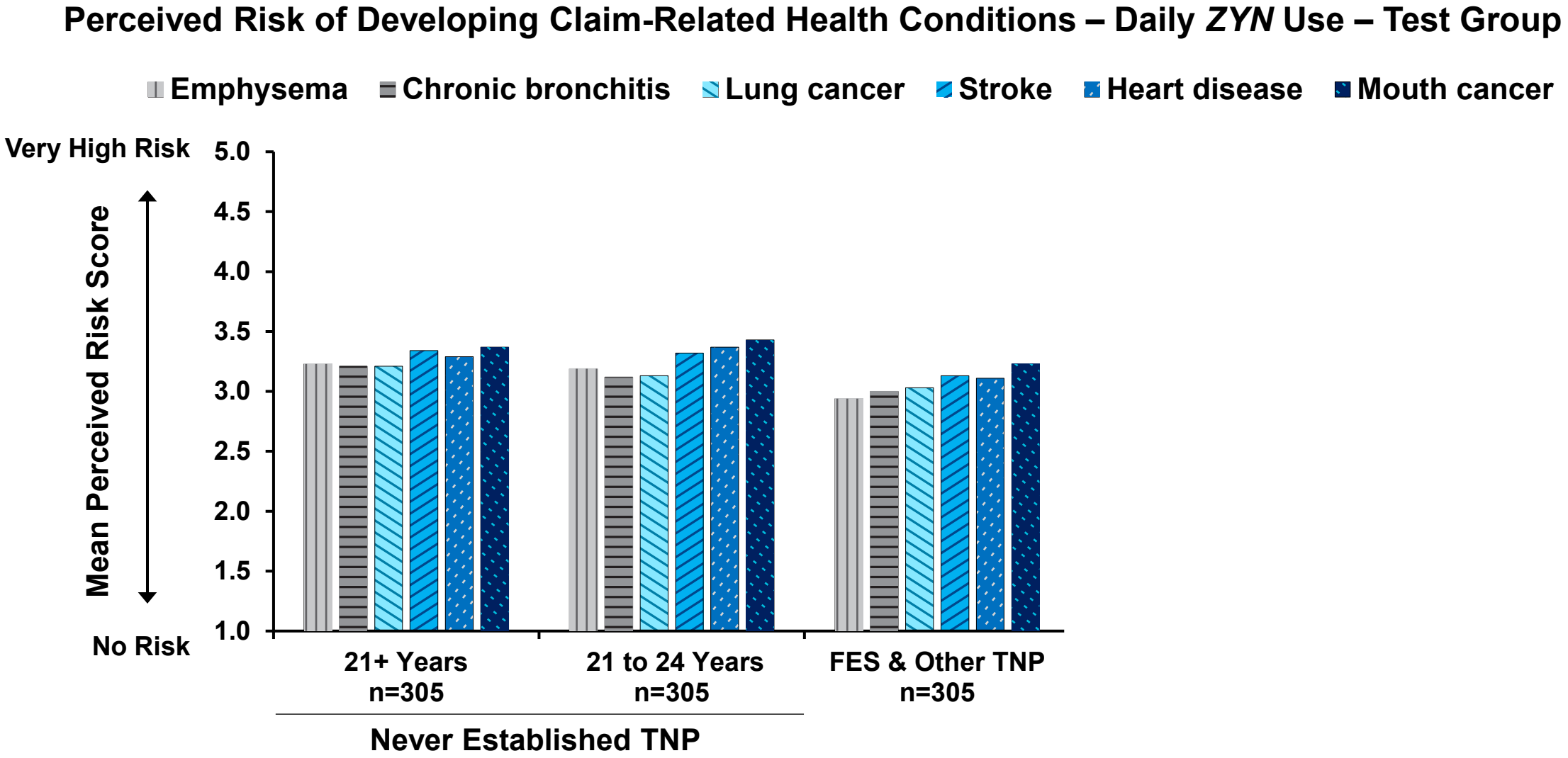
Source: *ZYN* Perceptions and Likelihood of Use Study Report. SMNA 5240072. N=3,450

Regardless of TNP Use, Adults Understand that *ZYN* Use Is Not Without Risk



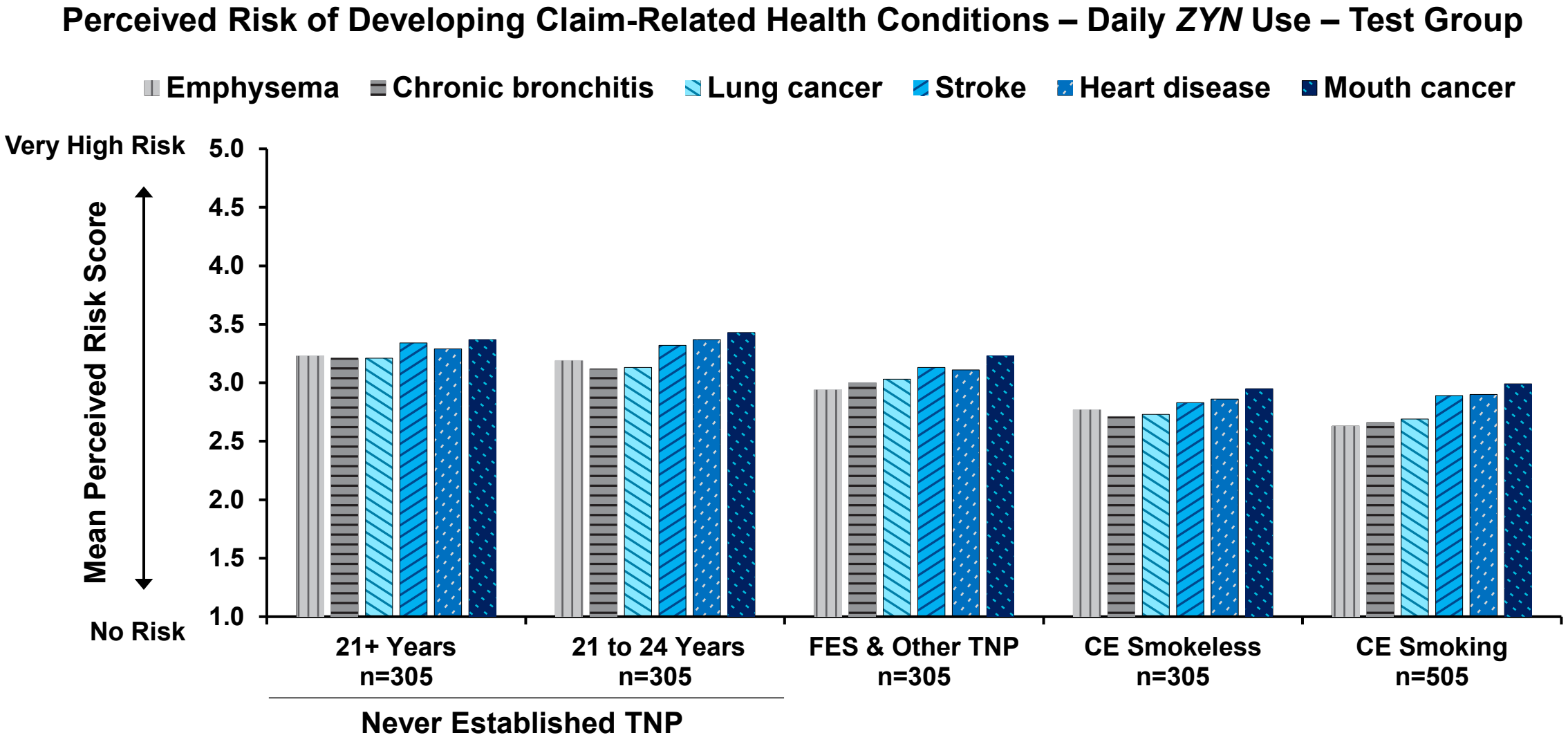
Source: SMNA 5240072. *ZYN* Perceptions and Likelihood of Use Study. Report Table 27.

Regardless of TNP Use, Adults Understand that *ZYN* Use Is Not Without Risk



Source: SMNA 5240072. *ZYN* Perceptions and Likelihood of Use Study. Report Table 27.

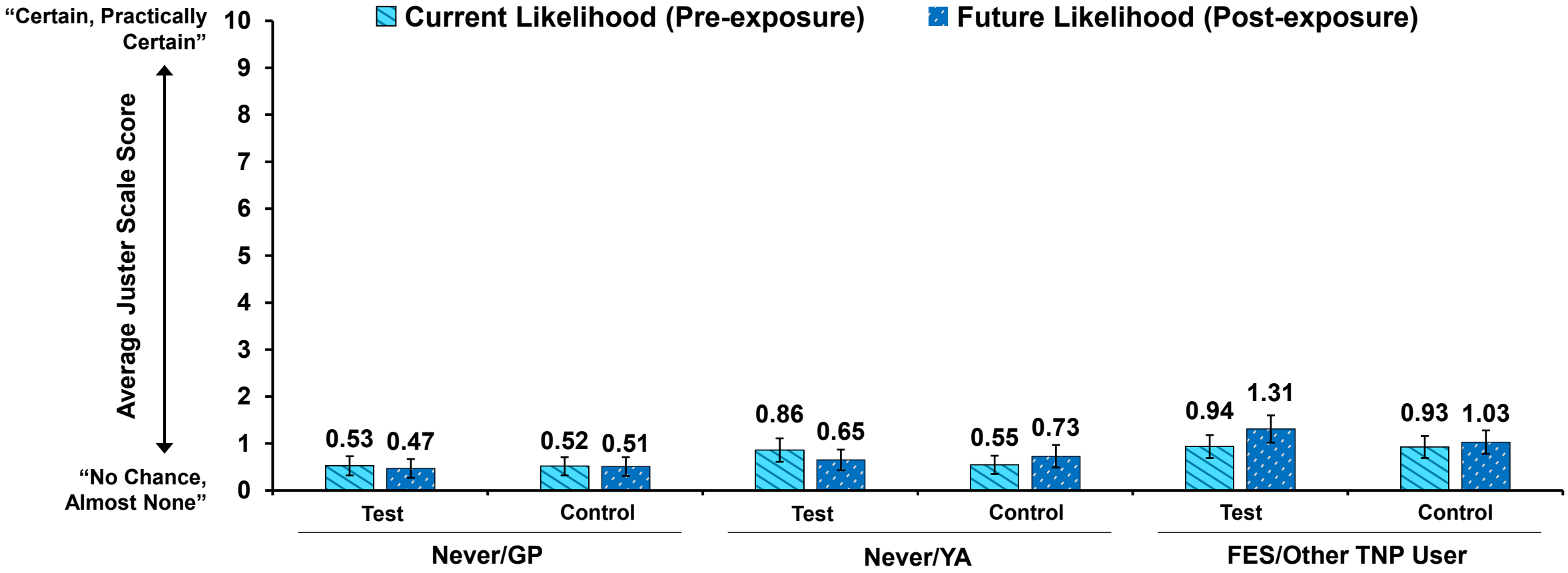
Regardless of TNP Use, Adults Understand that *ZYN* Use Is Not Without Risk



Source: SMNA 5240072. *ZYN* Perceptions and Likelihood of Use Study. Report Table 27.

Former Smokers & Never Users Have Low-to-No Intention to Use *ZYN* Either Before or After Exposure to the Modified Risk Claim

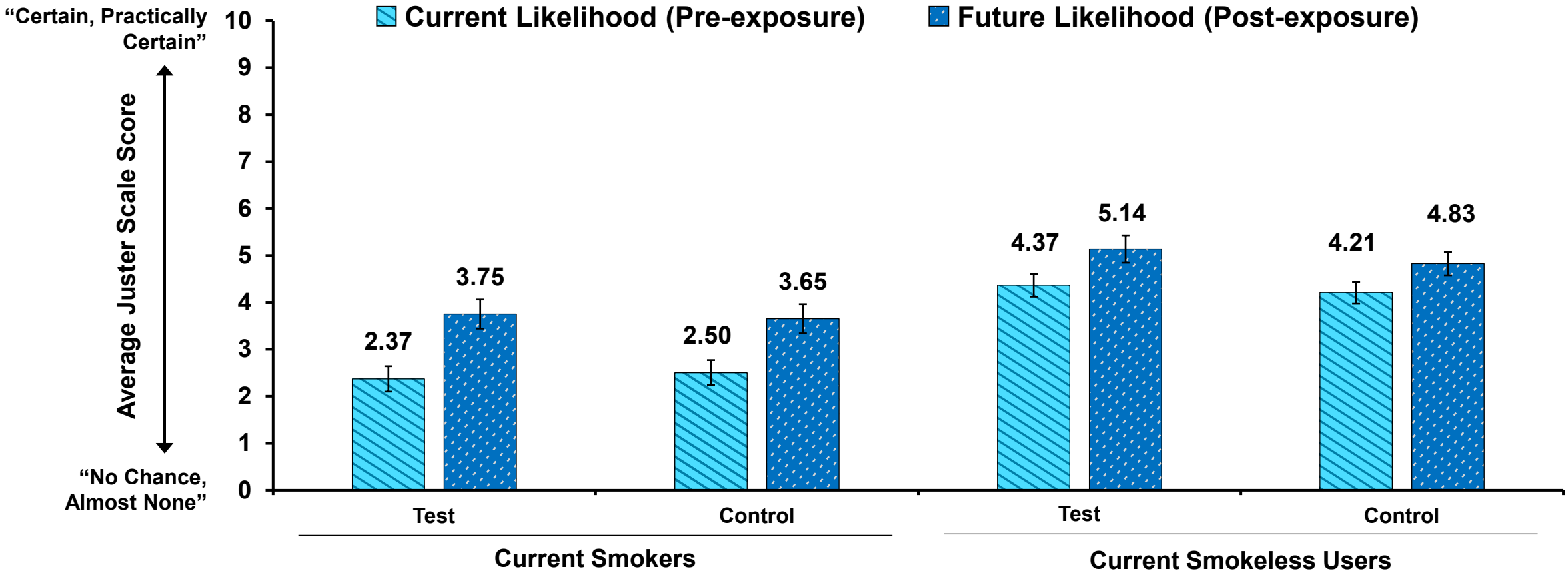
Pre-Exposure Current Intention to Use Nicotine Pouches and Post-Exposure Future Intention to Use *ZYN* among Test (w/ MRTP Claim) and Control (w/o MRTP Claim) Groups



FES/Other TNP User includes FES (former established smokers) who do not currently use any TNP, FES who use other TNP, and other TNP users (i.e., not cigarettes or smokeless tobacco).
Never/GP is defined as an adult (≥21 years) who has never established use of any TNP in their lifetime.
Never/YA is a subset of "Never/GP" that includes only those between the ages of 21 and 24 years.
Source: *ZYN* Perceptions and Likelihood of Use Study. SMNA 5240072. Report Table 15.

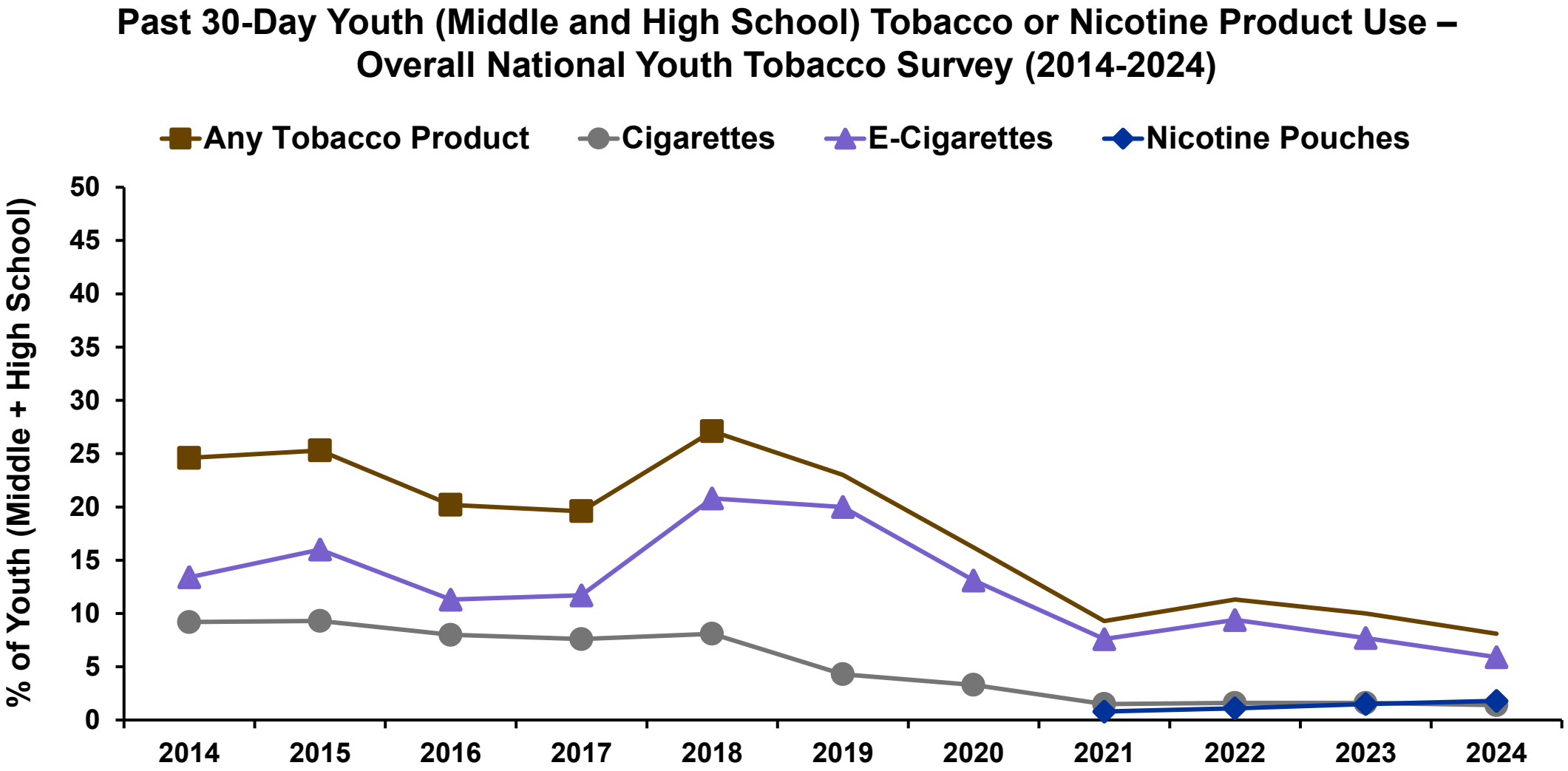
Increased Intention to Use *ZYN* After Viewing Product Information Among Adults Who Smoke or Use Smokeless Tobacco

Pre-Exposure Current Intention to Use Nicotine Pouches and Post-Exposure Future Intention to Use *ZYN* among Test (w/ MRTP Claim) and Control (w/o MRTP Claim) Groups



Current Smokers defined as having smoked ≥100 cigarettes in their lifetime and currently smoke "Every day" or "Some days".
Current Smokeless Users defined as currently using any smokeless tobacco product "Every day" or "Some days" and has not smoked ≥100 cigarettes in their lifetime.
Source: SMNA 5240072. *ZYN* Perceptions and Likelihood of Use Study. Report Table 15.

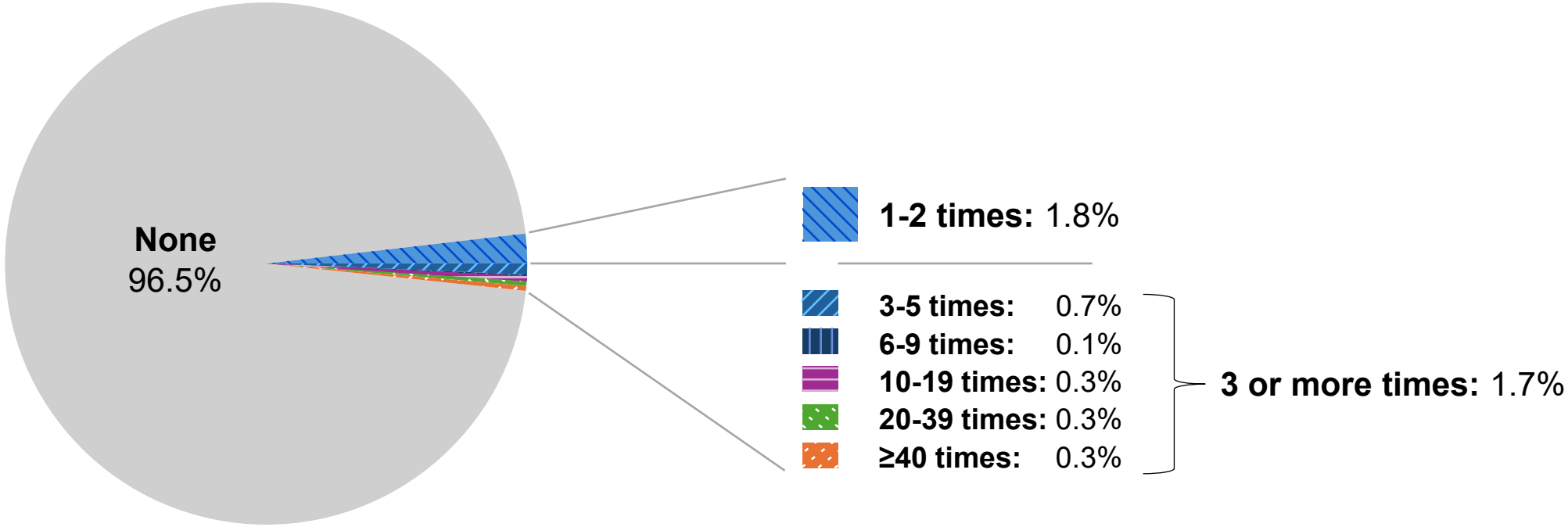
Since Launch in 2014, *ZYN* Use Among Youth in the U.S. Remains Low



Source: National Youth Tobacco Survey (NYTS).

ZYN Use Among Youth in U.S. Remains Low and Infrequent

Nicotine Pouch Use Occasions in the Past 30-Days among 12th Grade Students
Monitoring the Future (2024)



Source: Miech, R. A., Johnston, L. D., Patrick, M. E., & O'Malley, P. M. (2025). Monitoring the Future national survey results on drug use, 1975–2024: Overview and detailed results for secondary school students. Monitoring the Future Monograph Series. Ann Arbor, MI: Institute for Social Research, University of Michigan. Available at: https://monitoringthefuture.org/results/annual-reports/

Using *ZYN* instead of cigarettes puts you at a lower risk of mouth cancer, heart disease, lung cancer, stroke, emphysema, and chronic bronchitis.

1. Scientific Evidence Substantiates the Proposed Claim
2. Adults Who Smoke Understand the Proposed Claim
3. *ZYN* Users Switch From or Reduce Cigarette Use
4. Proposed Claim Does Not Increase Appeal to Nonusers

Responsible Marketing and Communicating the Claim

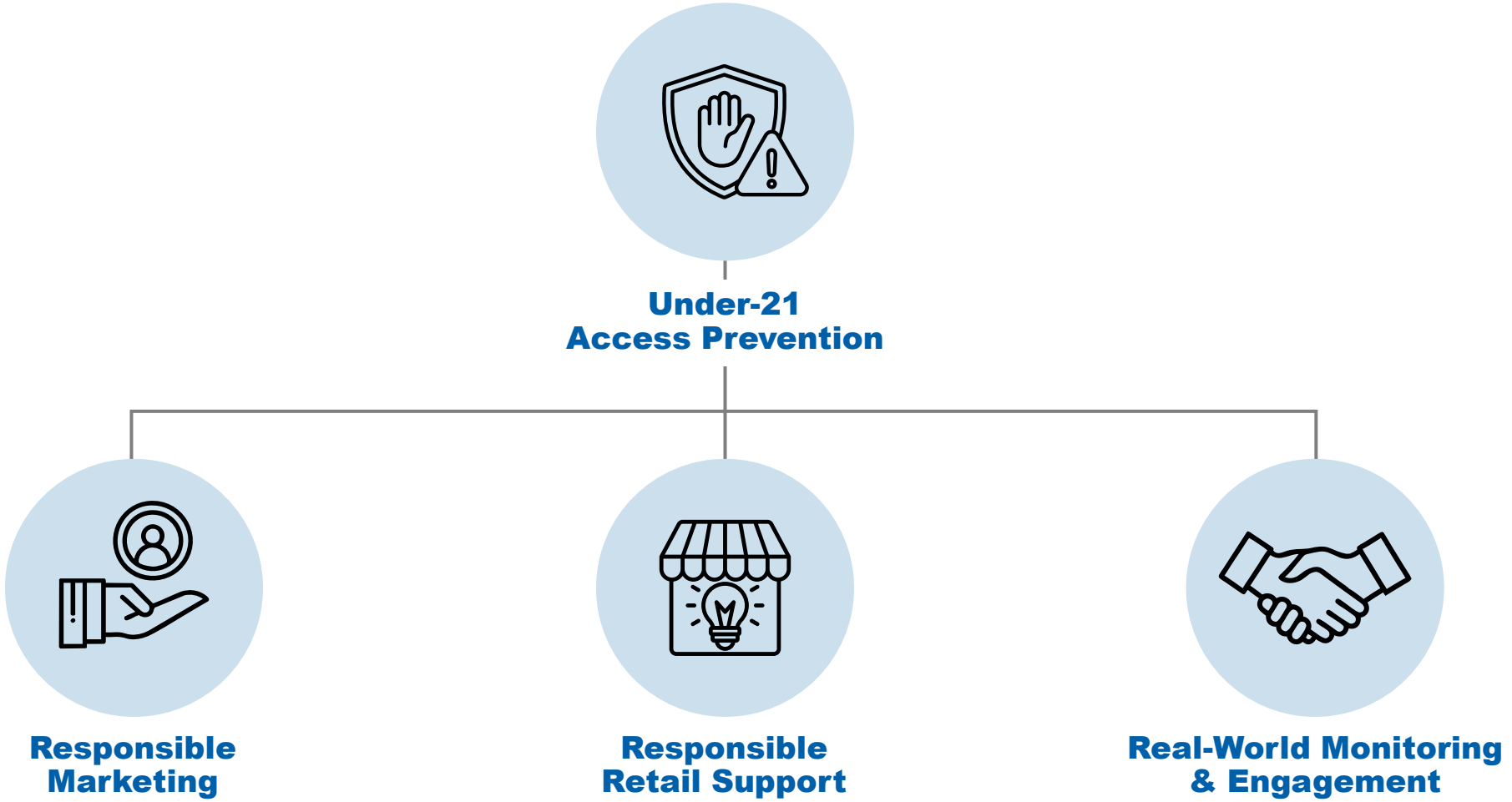
Keagan Lenihan
Vice President and Chief External Affairs Officer, U.S.

Marketing: Informing Adults Who Smoke

Why Is It Important for Adults Who Smoke to Understand the Relative Risks of Tobacco Products?

Many people who use tobacco products have misperceptions about the varying risks of tobacco products, which may prevent them from switching to a lower-risk alternative. Adults who smoke who fully switch from cigarettes to a lower-risk alternative can generally reduce their health risk and exposure to toxic and cancer-causing chemicals.

PMI U.S. Commitment To Responsibility



Our Commitment to Responsible Marketing



PMI U.S. Marketing Commitments include:

- We direct our marketing of products to those aged 21 and over
- We limit our own social media presence to platforms that enable age-restricted controls
- We require that our advertising features only individuals aged 35 or older
- We do not pay social media influencers to endorse our products
- We enforce independent online age verification (21+) for our branded websites
- We require ID checks at our own events and all 1:1 direct consumer engagements

ZYN Marketing Plans – APPH



"After reviewing the marketing plans submitted by the applicant, the CTP Office of Health Communication and Education (OHCE) concluded that **the applicant proposes directing its marketing to its target audience and proposes measures to limit youth exposure to the products' labeling, advertising, marketing, and promotion.**"

– FDA ZYN PMTA TPL Review, page 7 (2025)

FDA Reporting Requirements

- **Ongoing, collaborative oversight with FDA**
  - All final full-color advertising, marketing, and promotional materials.
  - A summary of all formative consumer research studies related to new labeling, advertising, marketing, and promotional materials.
  - A summary of the products' labeling, advertising, marketing, and promotional materials.
  - A description of all advertising and marketing plans.
  - An analysis of the actual delivery of advertising impressions.

Communicating the Claim: Existing Channels



Digital Property

Brand website



Point-of-Sale

Face-to-face



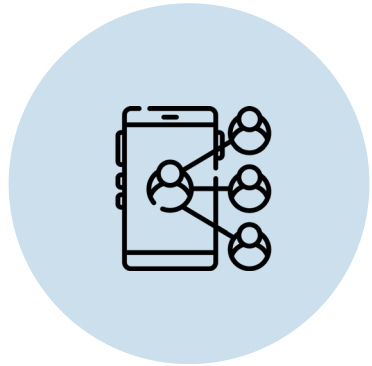
Email & Direct Mail

to 21+ age-verified consumers



Print & Digital Ads

where at least 85% are age 21+



Shared Digital Properties

Social Media

Using *ZYN* instead of cigarettes puts you at a lower risk of mouth cancer, heart disease, lung cancer, stroke, emphysema, and chronic bronchitis.

Using *ZYN* instead of cigarettes puts you at a lower risk of mouth cancer, heart disease, lung cancer, stroke, emphysema, and chronic bronchitis.

Adults who smoke need accurate information about different tobacco products and the relative risks associated with them to make informed decisions that can impact their health.

Conclusion

Keagan Lenihan
Vice President and Chief External Affairs Officer, U.S.

1 Scientific Evidence Substantiates the Proposed Claim

1. Scientific Evidence Substantiates the Proposed Claim

2. Adults Who Smoke Understand the Proposed Claim

1. Scientific Evidence Substantiates the Proposed Claim
2. Adults Who Smoke Understand the Proposed Claim
3. *ZYN* Users Switch From or Reduce Cigarette Use

1. Scientific Evidence Substantiates the Proposed Claim
2. Adults Who Smoke Understand the Proposed Claim
3. *ZYN* Users Switch From or Reduce Cigarette Use
4. Proposed Claim Does Not Increase Appeal to Nonusers

Evidence and data demonstrates that an MRGO for *ZYN* should be granted

Using *ZYN* instead of cigarettes puts you at a lower risk of mouth cancer, heart disease, lung cancer, stroke, emphysema, and chronic bronchitis.

Adults who smoke need accurate information about different tobacco products and the relative risks associated with them to make informed decisions that can impact their health.

PMI | U.S.

ZYN MRTP Application

Tobacco Products Scientific Advisory Committee Meeting

Swedish Match USA, Inc.

January 22nd, 2026