

Tobacco Harm Reduction Potential of the Ploom[®] System in the U.S.

Sonny Sisodiya, PhD

Regulatory Science Integration Director
Japan Tobacco International

Joshua Karelitz, PhD

Principal Regulatory Scientist II
Altria Client Services

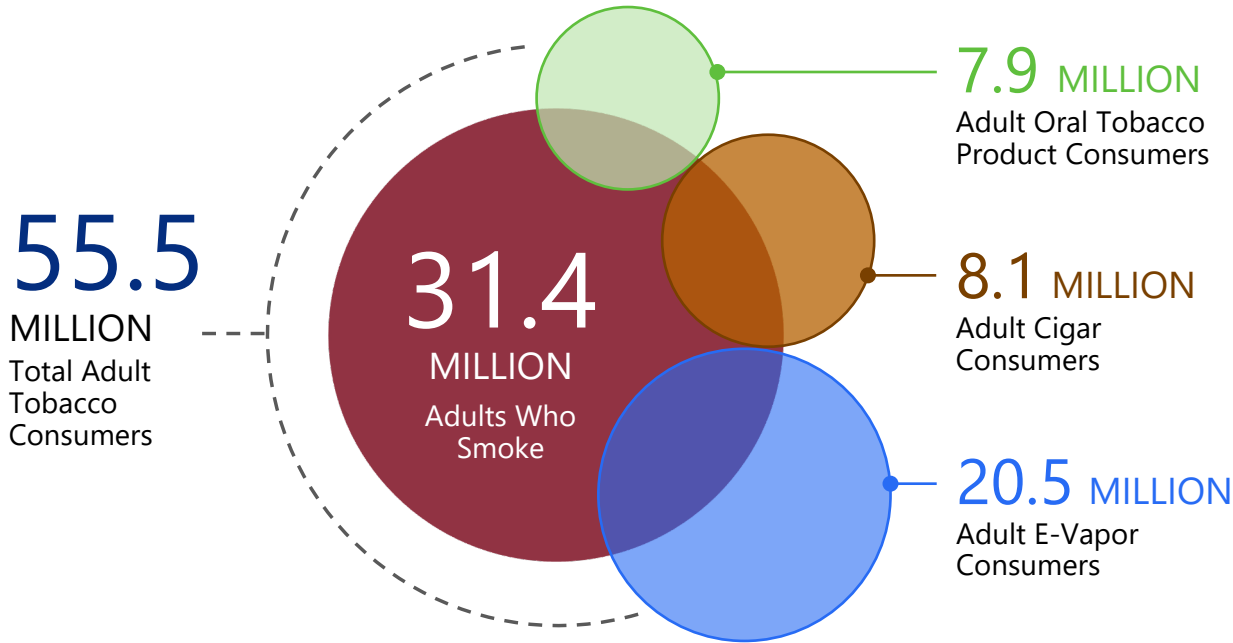


PARTNERSHIP

Between
JT Group
and Altria
to Bring Ploom®
System to U.S.
Adults Who Smoke
Age 21+



Population of Adults Who Smoke in The U.S. is Still Sizeable



Source: Altria Client Services LLC Adult Tobacco Consumer Tracker (ALCS ATCT) – Q2, 2025
Overlaps do not represent real number of dual users

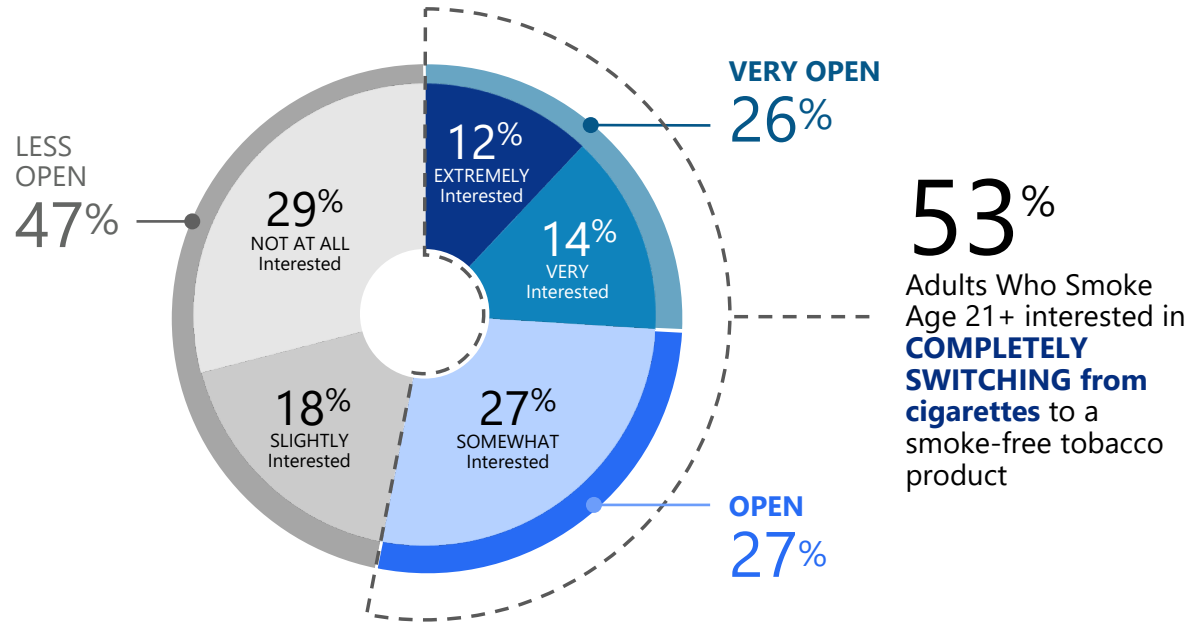
Altria Client Services & JTI Group | Next Generation Nicotine Delivery | June 2025

Horizon Innovations LLC is a joint venture between Philip Morris USA Inc. and JTI (US) Holding Inc. for the commercialization of Ploom® in the U.S. market.

There is Interest Among U.S. Adults Who Smoke in Completely Switching to Smoke-free Products

? ADULTS WHO SMOKE 21-54 n=4037

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)?



Adults Who Smoke Age 21+ interested in **COMPLETELY SWITCHING** from **cigarettes** to a smoke-free tobacco product

ALCS Consumer Market Insights Data.

Altria Client Services & JTI Group | Next Generation Nicotine Delivery | June 2025

Horizon Innovations LLC is a joint venture between Philip Morris USA Inc. and JTI (US) Holding Inc. for the commercialization of Ploom® in the U.S. market.

The Ploom[®] System

Ploom[®] Device

Heated Tobacco Sticks



Tobacco-Flavored

Tobacco 1

Tobacco 2

Menthol-Flavored

Menthol 1

Menthol 2

Scientific Framework



Constituent reduction



The product

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



Individual risk reduction

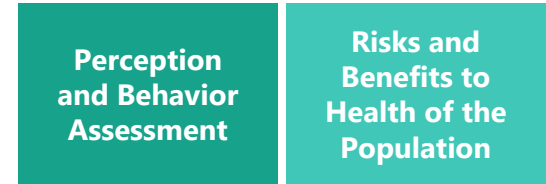


Exposure and health risk

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



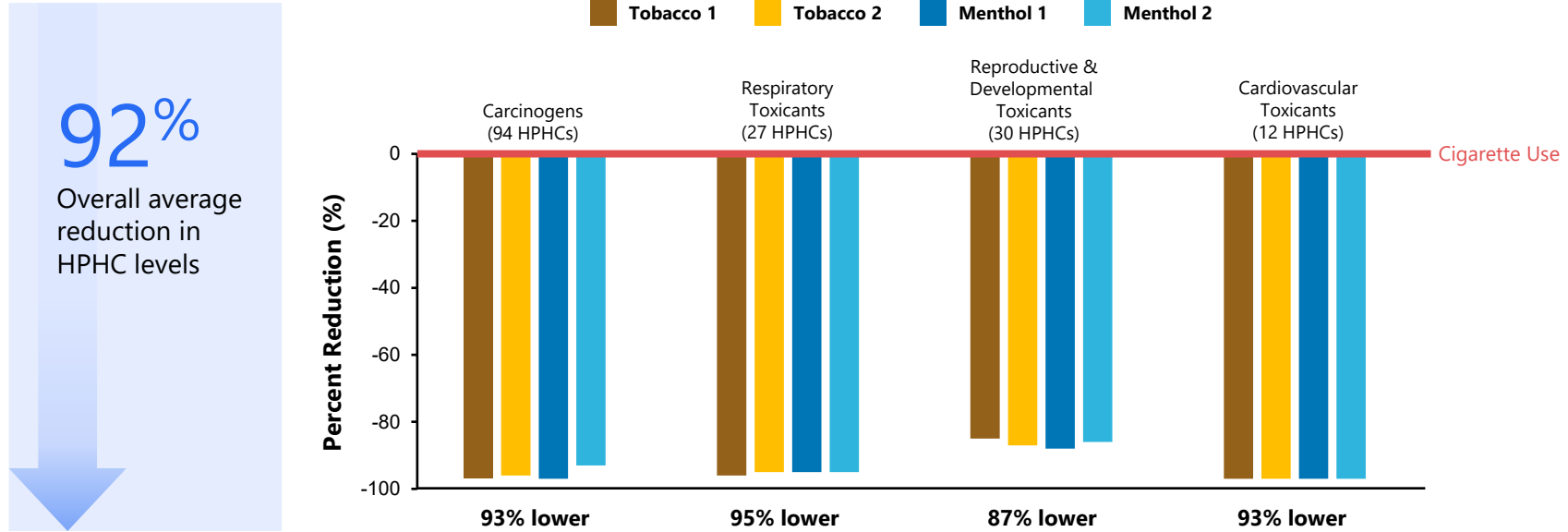
Population harm reduction



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

Harmful Chemicals in the Ploom[®] System Mainstream Aerosol Are 92% Lower, Compared to Cigarette Smoke

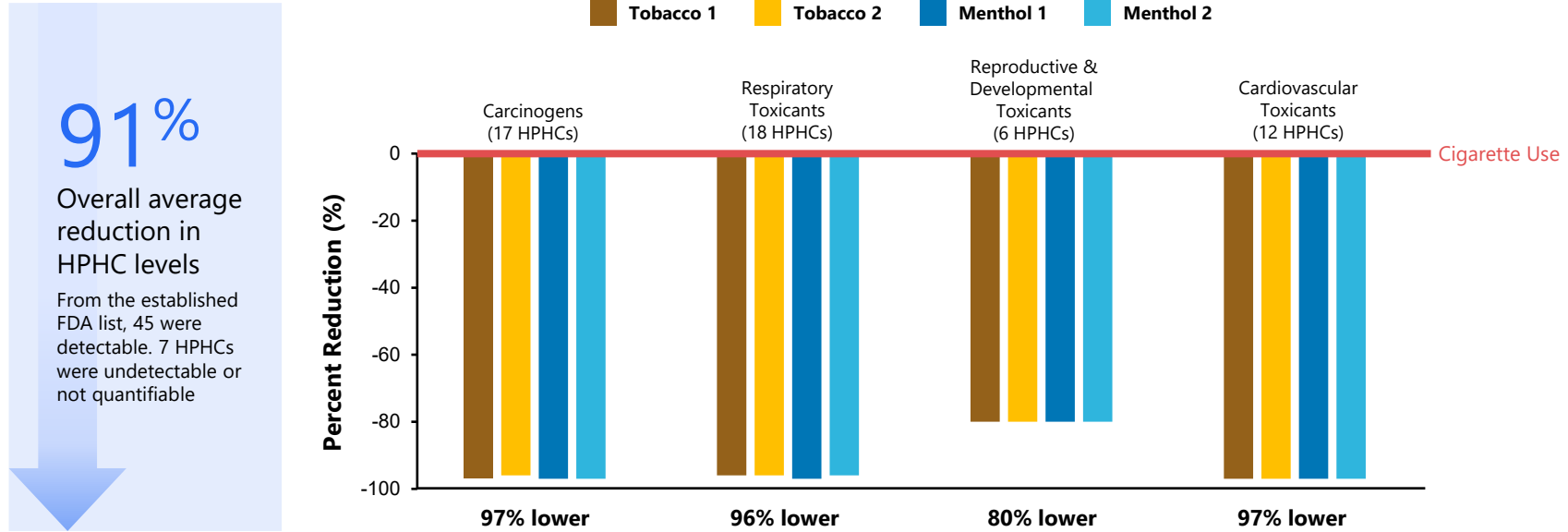


Source: Nonclinical Study Report 136. Bars represent average percent reductions in HPHCs for tobacco and menthol flavor variant for HPHCs on the established FDA list. Carcinogens: 39/94 HPHCs were not detectable in all four flavor variants and the combustible cigarette comparator, 1R6F. Respiratory: 5/27 HPHCs were not quantifiable or detectable in all four flavor variants and the combustible cigarette comparator, 1R6F. Reproductive & Developmental: 14/26 HPHCs were not quantifiable or detectable in all four flavor variants and the combustible cigarette comparator, 1R6F. Cardiovascular: 1/12 HPHCs were not quantifiable or detectable in all four flavor variants and the combustible cigarette comparator, 1R6F. Nicotine and chromium (below LOQ) are excluded. Some HPHCs have more than one classification and are included for each of their classifications HPHC=Harmful and Potentially Harmful Constituents.

Harmful Chemicals Reduced by 91% in Ploom[®] System Sidestream Aerosol Compared to Cigarette Smoke



CONSTITUENT REDUCTION



Source: Nonclinical Study Report 147. Bars represent average percent reductions in HPHCs for all tobacco and menthol flavor variants. NOTE: 52 methods were available to determine HPHCs in sidestream aerosol, 26 HPHCs from the established FDA list. Carcinogens: 4/25 HPHCs were not detectable in all four flavor variants and the combustible cigarette comparator, 1R6F. Respiratory: 3/21 HPHCs were not quantifiable or detectable in all four flavor variants and the combustible cigarette comparator, 1R6F. Reproductive & Developmental: 3/9 HPHCs were not quantifiable or detectable in all four flavor variants and the combustible cigarette comparator, 1R6F. Cardiovascular: 4/12 HPHCs were not quantifiable or detectable in all four flavor variants and the combustible cigarette comparator, 1R6F. Some HPHCs have more than one classification and are included for each of their classifications.

FDA=Food and Drug Administration; HPHC=Harmful and Potentially Harmful Constituents.

Altria Client Services & JTI Group | Next Generation Nicotine Delivery | June 2025

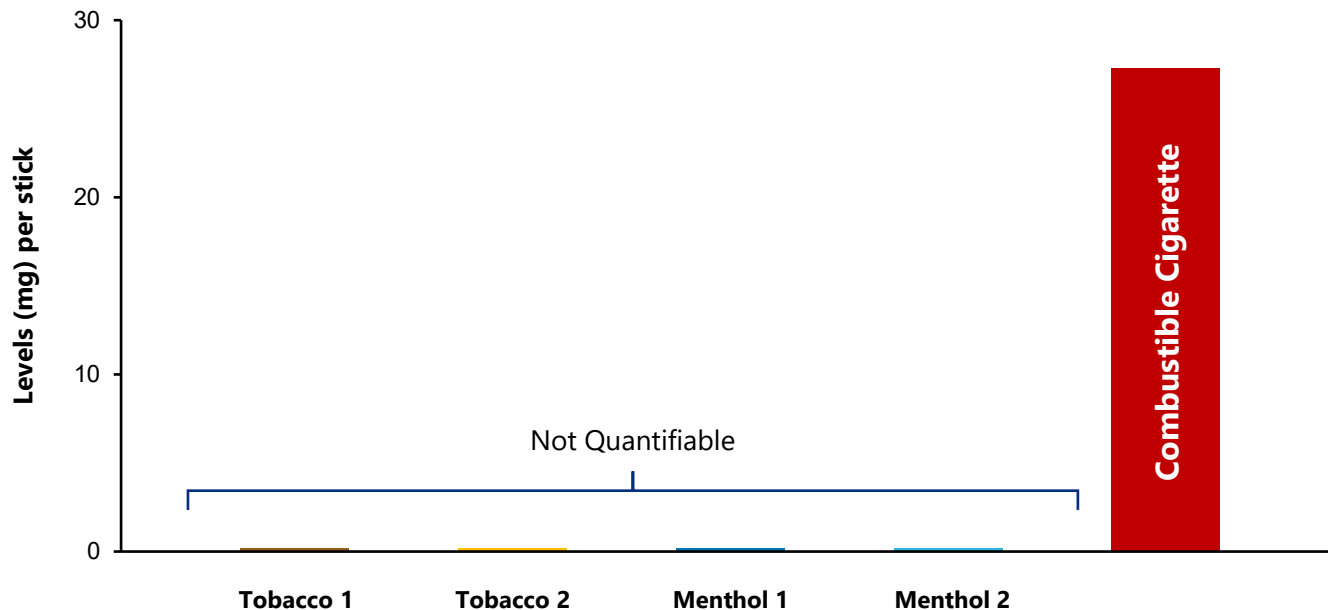
Horizon Innovations LLC is a joint venture between Philip Morris USA Inc. and JTI (US) Holding Inc. for the commercialization of Ploom[®] in the U.S. market.



Carbon Monoxide in Ploom[®] System Mainstream Aerosol is NOT Quantifiable



99%
Overall average
reduction

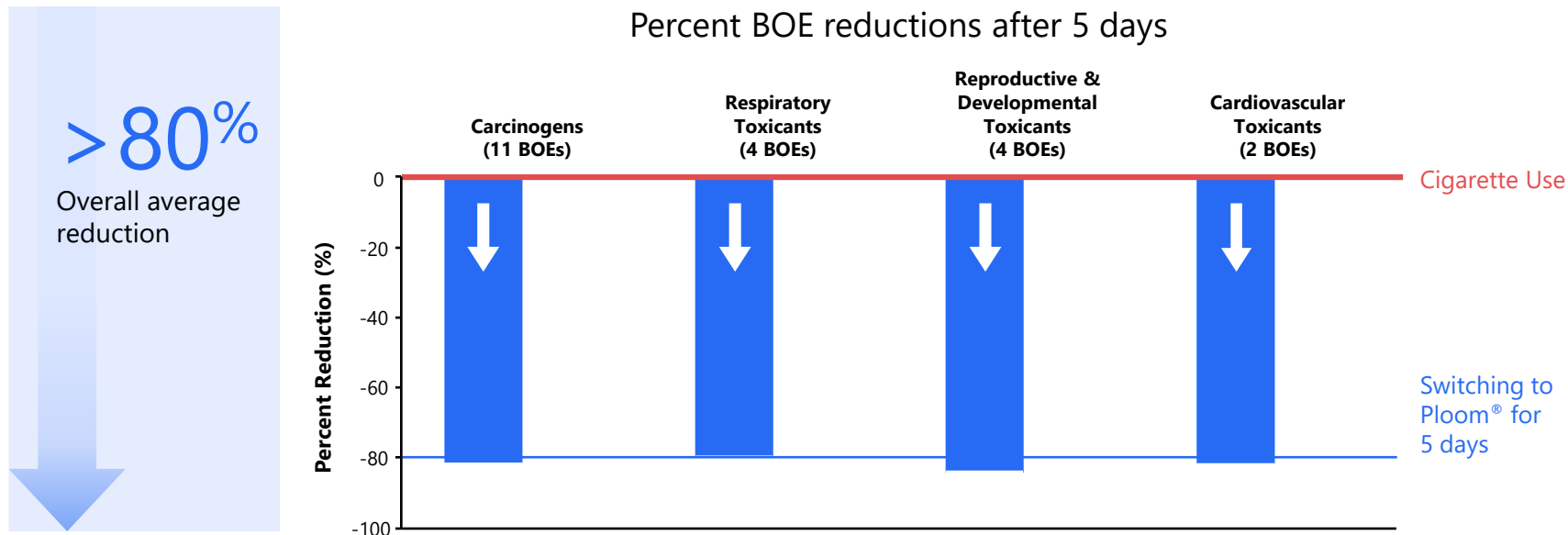


Source: Nonclinical Study Report 136. Bars represent the average levels of CO for each flavor.

Altria Client Services & JTI Group | Next Generation Nicotine Delivery | June 2025

Horizon Innovations LLC is a joint venture between Philip Morris USA Inc. and JTI (US) Holding Inc. for the commercialization of Ploom[®] in the U.S. market.

Biomarkers of Exposure are Significantly Reduced Among Switchers Based on Clinical Assessment



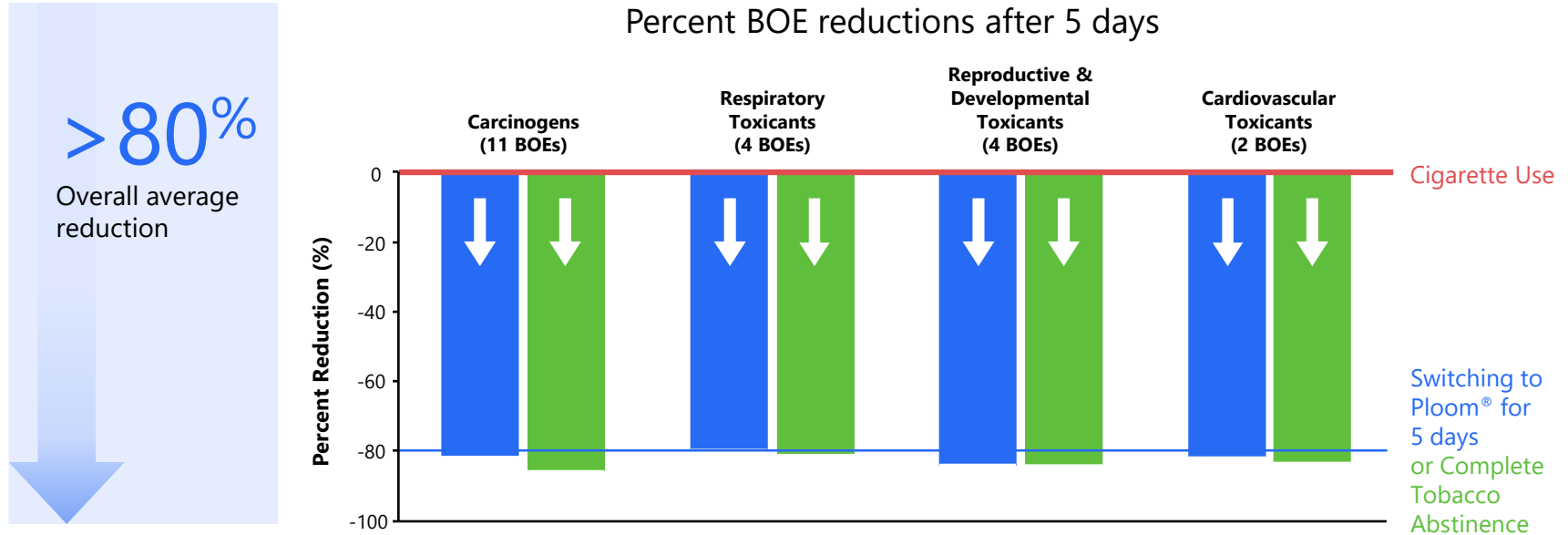
Source: ALCS Clinical Study Report ALCS-REG-23-07-HT. Blue Bars represent median percent reductions in measured BOEs when adult smokers completely switched to Ploom for 5 days in our clinical study. Green Bars represent median percent reductions in measured BOEs when adult smokers abstained from all tobacco for 5 days in our clinical study. Some BOEs have more than one classification and are included for each of their classifications. Nicotine BOE is not included. BOE=Biomarkers of Exposure.

Altria Client Services & JTI Group | Next Generation Nicotine Delivery | June 2025

Horizon Innovations LLC is a joint venture between Philip Morris USA Inc. and JTI (US) Holding Inc. for the commercialization of Ploom® in the U.S. market.



BOE Reduction When AS Switch to Ploom[®] System Comparable to Abstaining From all Tobacco Use Except for Nicotine Exposure



Percent Reductions in BOEs among adult smokers who **completely switched to Ploom[®]** were comparable to **complete tobacco abstinence**, excluding nicotine

Source: ALCS Clinical Study Report ALCS-REG-23-07-HT. Blue Bars represent median percent reductions in measured BOEs when adult smokers completely switched to Ploom for 5 days in our clinical study. Green Bars represent median percent reductions in measured BOEs when adult smokers abstained from all tobacco for 5 days in our clinical study. Some BOEs have more than one classification and are included for each of their classifications. Nicotine BOE is not included. BOE=Biomarkers of Exposure.

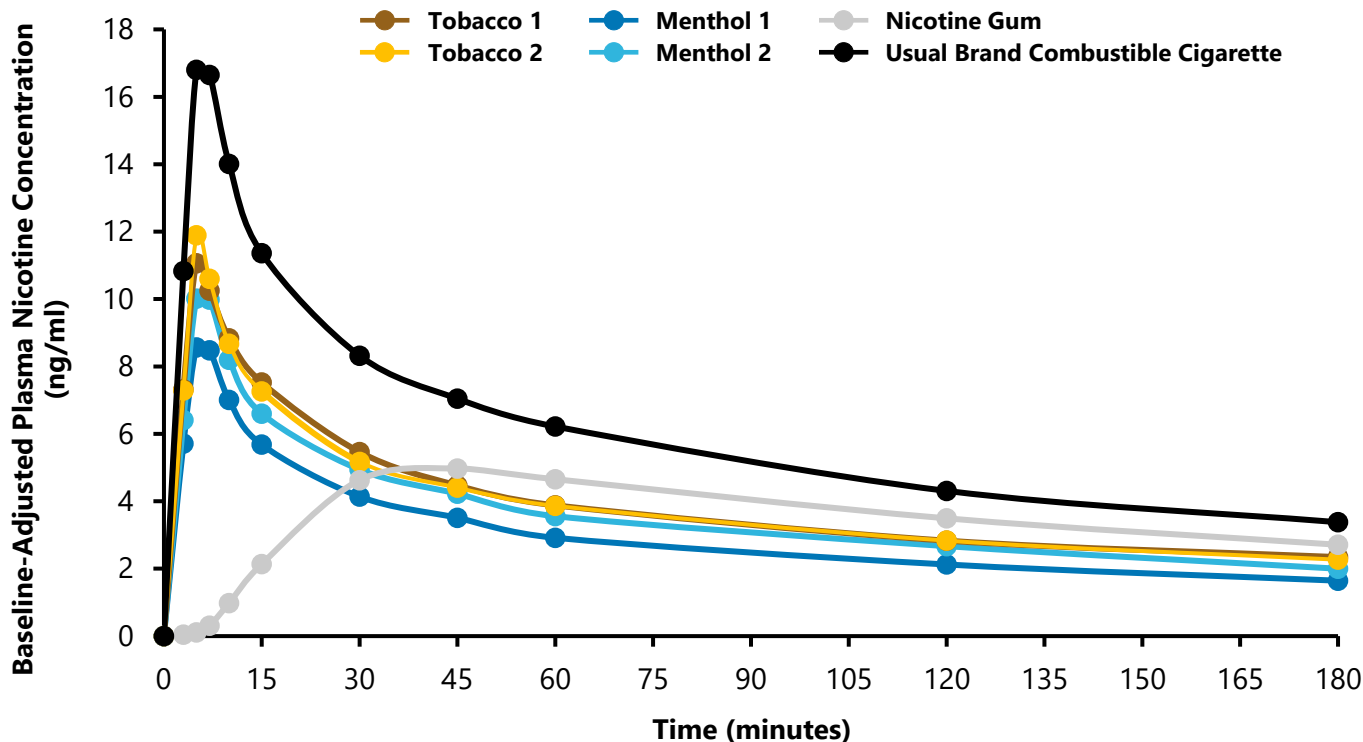
Altria Client Services & JTI Group | Next Generation Nicotine Delivery | June 2025

Horizon Innovations LLC is a joint venture between Philip Morris USA Inc. and JTI (US) Holding Inc. for the commercialization of Ploom[®] in the U.S. market.

Ploom® System Efficiently Delivers Nicotine to the Blood but Does Not Exceed that of Combustible Cigarettes



INDIVIDUAL RISK REDUCTION



Source: ALCS Clinical Study Report ALCS-REG-23-08-HT. Graph generated using baseline adjusted arithmetic values of plasma nicotine concentrations at each time point.

Altria Client Services & JTI Group | Next Generation Nicotine Delivery | June 2025

Horizon Innovations LLC is a joint venture between Philip Morris USA Inc. and JTI (US) Holding Inc. for the commercialization of Ploom® in the U.S. market.

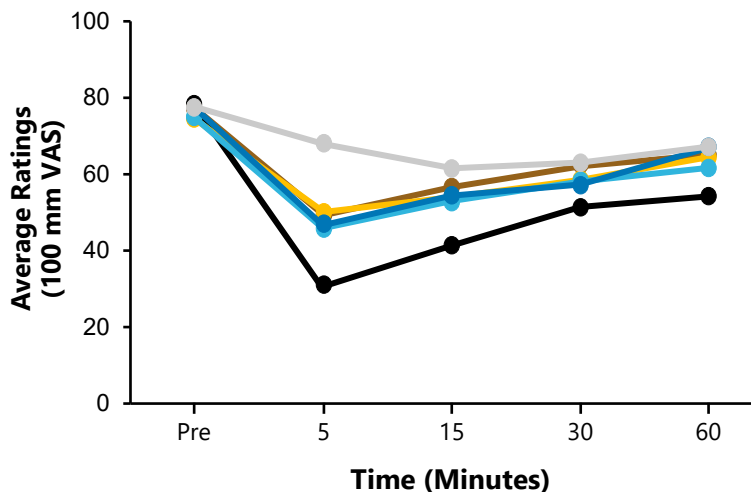


Ploom® System Reduces Craving and is Liked, but to a Lesser Extent than Combustible Cigarettes

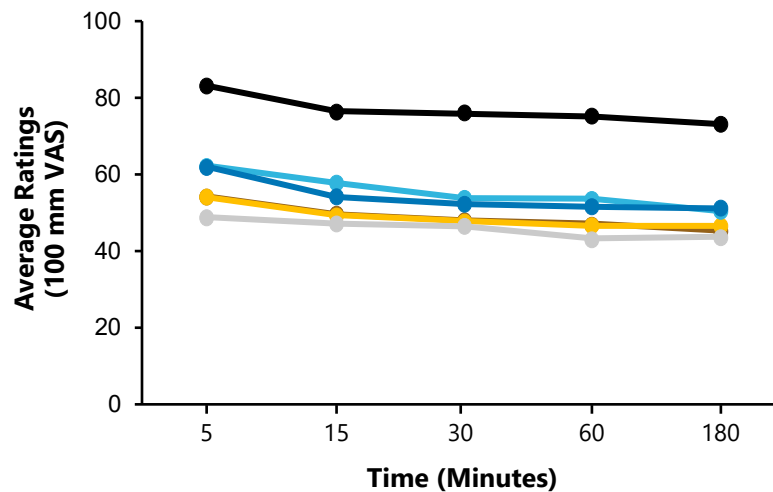


- Tobacco 1
- Menthol 1
- Nicotine Gum
- Tobacco 2
- Menthol 2
- Usual Brand Combustible Cigarette

Cigarette Craving



Product Liking



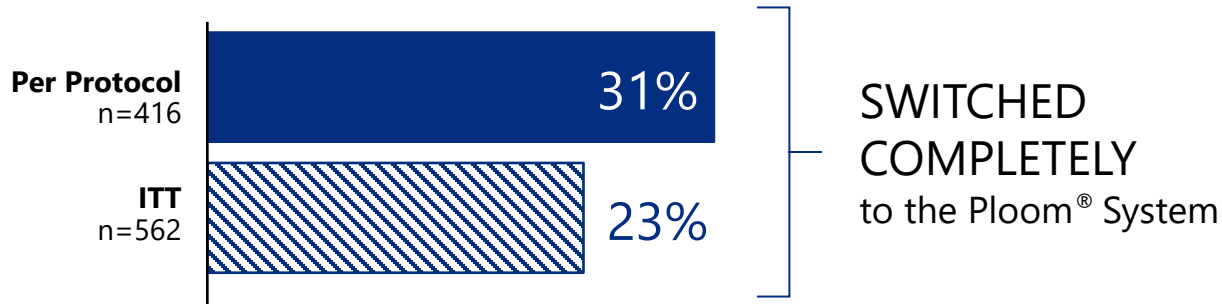
Source: ALCS Clinical Study Report ALCS-REG-23-08-HT.

Altria Client Services & JTI Group | Next Generation Nicotine Delivery | June 2025

Horizon Innovations LLC is a joint venture between Philip Morris USA Inc. and JTI (US) Holding Inc. for the commercialization of Ploom® in the U.S. market.



Many Adults Who Smoke Switched Completely

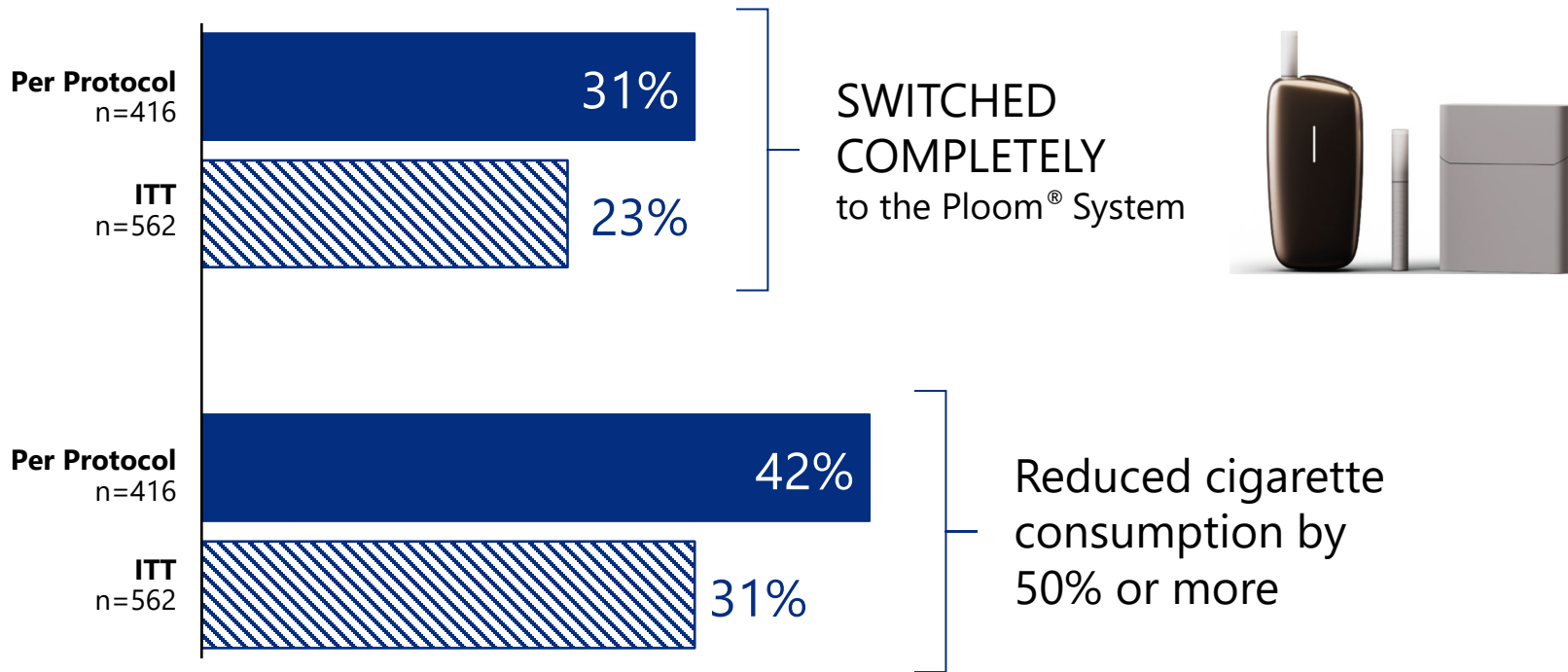


Source: ALCS Study Report ALCS-REG-23-13-HT. ITT=intention to treat. Per Protocol Sample included only those who completed the study; ITT sample included all enrolled at Week 1.

Altria Client Services & JTI Group | Next Generation Nicotine Delivery | June 2025

Horizon Innovations LLC is a joint venture between Philip Morris USA Inc. and JTI (US) Holding Inc. for the commercialization of Ploom® in the U.S. market.

Many Adults Who Smoke Switched Completely or Substantially Reduced Combustible Cigarette Consumption by $\geq 50\%$



Source: ALCS Study Report ALCS-REG-23-13-HT. ITT=intention to treat. Per Protocol Sample included only those who completed the study; ITT sample included all enrolled at Week 1.

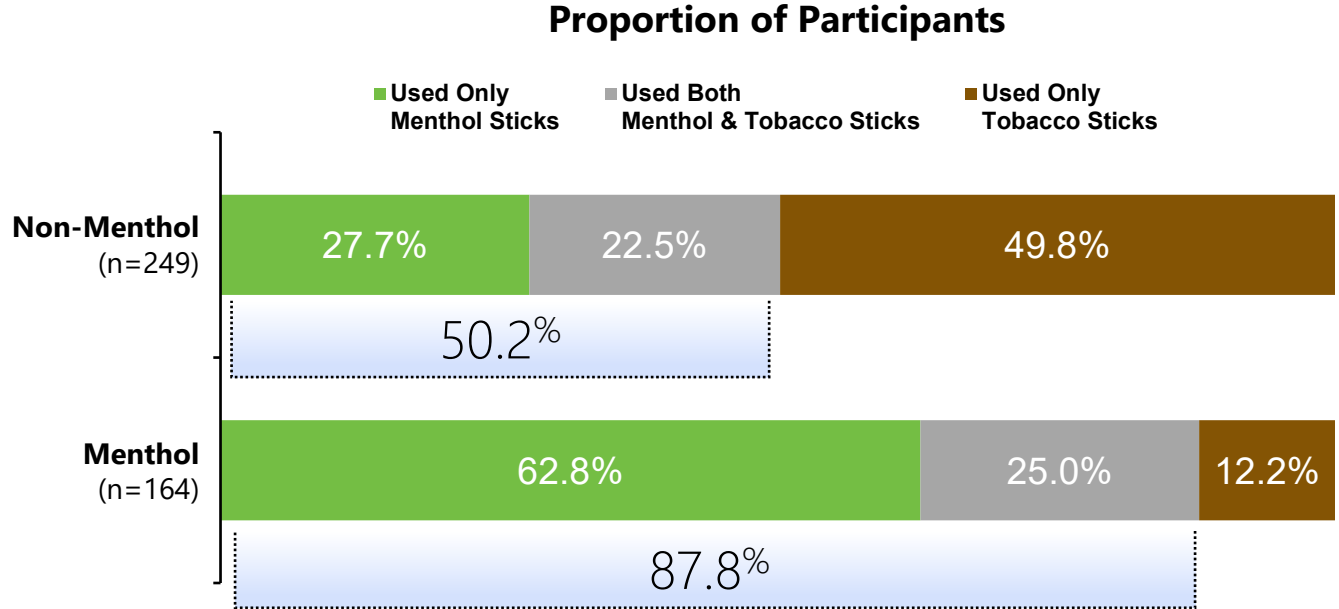
Altria Client Services & JTI Group | Next Generation Nicotine Delivery | June 2025

Horizon Innovations LLC is a joint venture between Philip Morris USA Inc. and JTI (US) Holding Inc. for the commercialization of Ploom® in the U.S. market.

Greater Reach of Menthol-Flavored Sticks in Week 6, Regardless of Incoming Combustible Cigarette Flavor Preference



Incoming Combustible Cigarette Preference



Source: ALCS Study Report ALCS-REG-23-13-HT.

Altria Client Services & JTI Group | Next Generation Nicotine Delivery | June 2025

Horizon Innovations LLC is a joint venture between Philip Morris USA Inc. and JTI (US) Holding Inc. for the commercialization of Ploom® in the U.S. market.

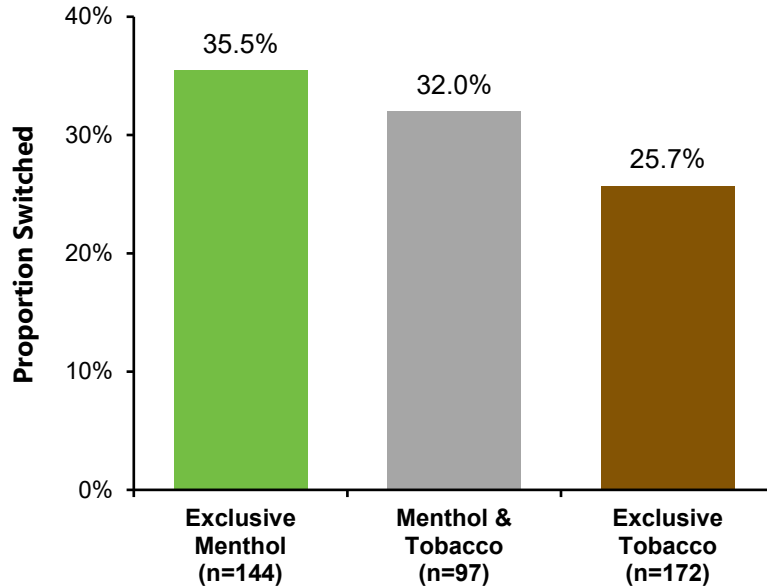


Higher Switching When Using Menthol-Flavored Ploom® System Relative to Tobacco-Flavored



Complete Switching at Week 6

(based on those who used Ploom® System in Week 6; n=413)



Source: ALCS Report 2024-AH-72.

Altria Client Services & JTI Group | Next Generation Nicotine Delivery | June 2025

Horizon Innovations LLC is a joint venture between Philip Morris USA Inc. and JTI (US) Holding Inc. for the commercialization of Ploom® in the U.S. market.

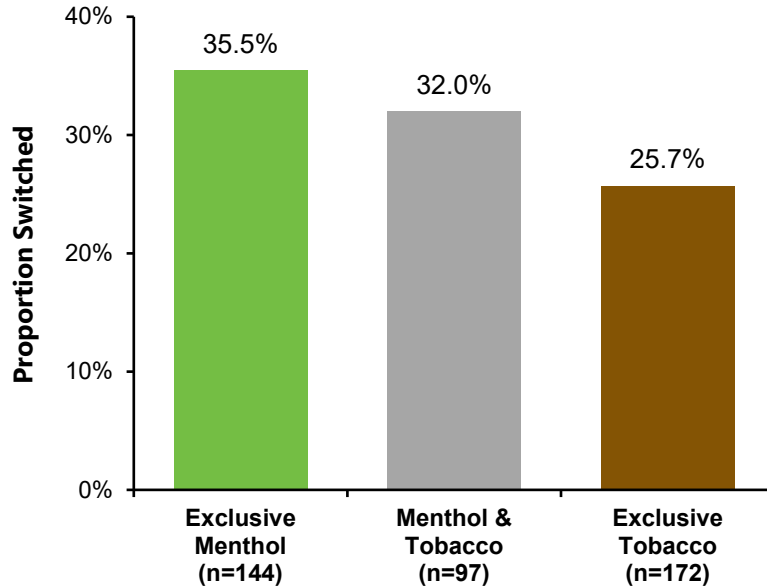


Higher Switching When Using Menthol-Flavored Ploom[®] System Relative to Tobacco-Flavored



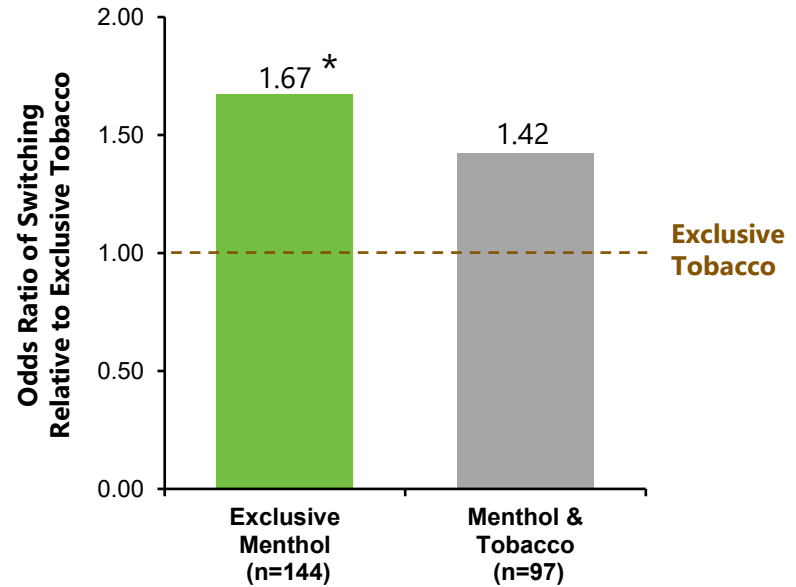
Complete Switching at Week 6

(based on those who used Ploom[®] System in Week 6; n=413)



Odds of Complete Switching at Week 6

(based on those who used Ploom[®] System in Week 6; n=413)



* Indicates statistically significant at $p < 0.05$

Source: ALCS Report 2024-AH-72.

Altria Client Services & JTI Group | Next Generation Nicotine Delivery | June 2025

Horizon Innovations LLC is a joint venture between Philip Morris USA Inc. and JTI (US) Holding Inc. for the commercialization of Ploom[®] in the U.S. market.

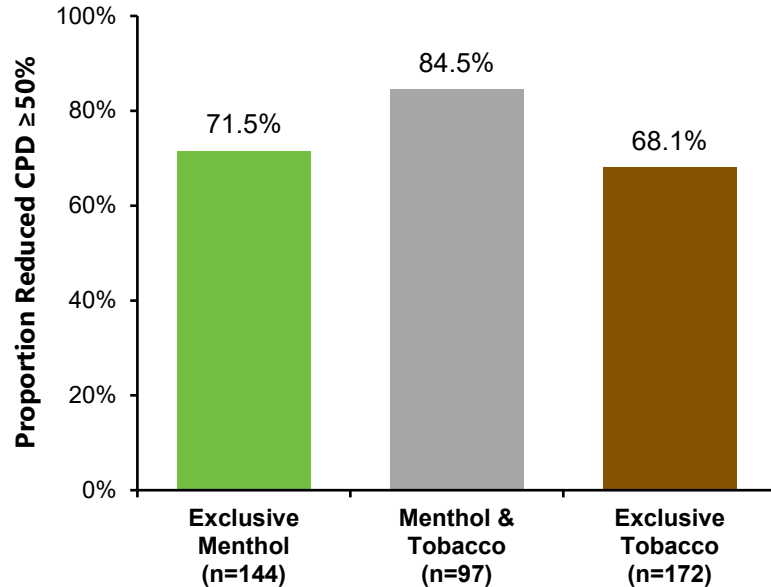


Use of Menthol- and Tobacco-Flavors Together Likely More Effective in Promoting $\geq 50\%$ CPD Reduction Relative to Tobacco-Flavor Alone



Reduced CPD by $\geq 50\%$ at Week 6

(based on those who used Ploom[®] System in Week 6; n=413)



Source: ALCS Report 2024-AH-72.

Altria Client Services & JTI Group | Next Generation Nicotine Delivery | June 2025

Horizon Innovations LLC is a joint venture between Philip Morris USA Inc. and JTI (US) Holding Inc. for the commercialization of Ploom[®] in the U.S. market.

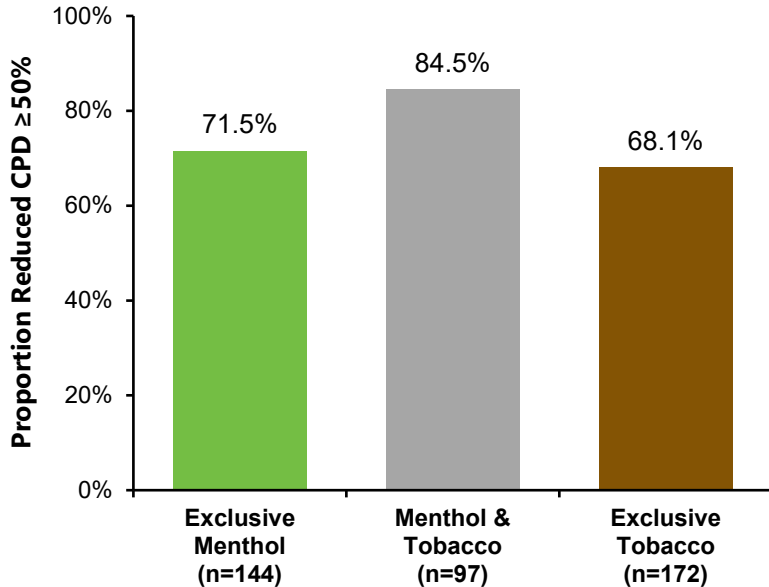


Use of Menthol- and Tobacco-Flavors Together Likely More Effective in Promoting $\geq 50\%$ CPD Reduction Relative to Tobacco-Flavor Alone



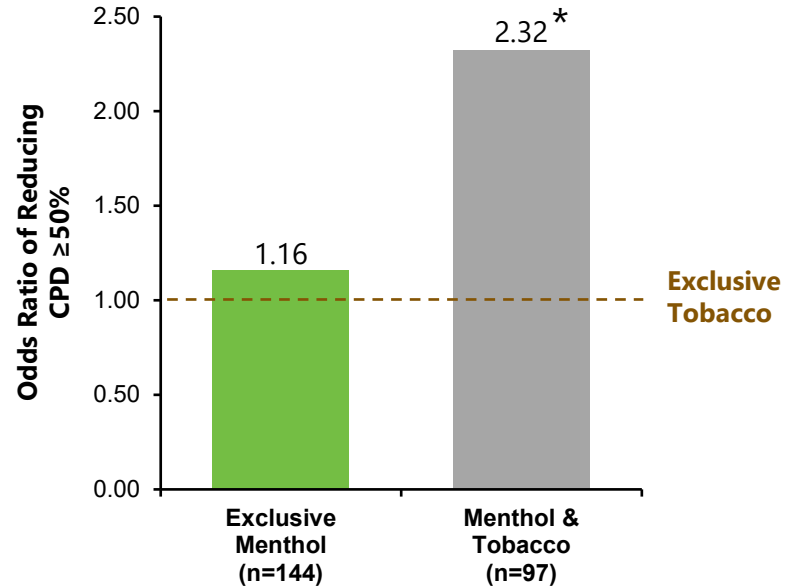
Reduced CPD by $\geq 50\%$ at Week 6

(based on those who used Ploom[®] System in Week 6; n=413)



Odds of Reducing CPD by $\geq 50\%$ at Week 6

(based on those who used Ploom[®] System in Week 6; n=413)



* Indicates statistically significant at $p < 0.05$

Source: ALCS Report 2024-AH-72.

Altria Client Services & JTI Group | Next Generation Nicotine Delivery | June 2025

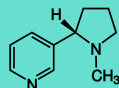
Horizon Innovations LLC is a joint venture between Philip Morris USA Inc. and JTI (US) Holding Inc. for the commercialization of Ploom[®] in the U.S. market.



Totality of the Evidence Demonstrates Abuse Liability of Ploom[®] System is Likely Lower than Combustible Cigarettes



ALA relied on nicotine exposure and subjective effects from using the Ploom[®] System



NICOTINE EXPOSURE

Pharmacokinetics (PK)



SUBJECTIVE EFFECTS

Pharmacodynamics (PD), Product Liking, Satisfaction, Craving, Withdrawal

ALA is also informed by switching potential and potential health risks



USE PATTERNS

Actual Use



HEALTH RISK ASSESSMENT

Chemical Analyses, BOE Study

ALA=Abuse Liability Assessment

Altria Client Services & JTI Group | Next Generation Nicotine Delivery | June 2025

Horizon Innovations LLC is a joint venture between Philip Morris USA Inc. and JTI (US) Holding Inc. for the commercialization of Ploom[®] in the U.S. market.

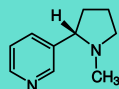


Totality of the Evidence Demonstrates Abuse Liability of Ploom[®] System is Likely Lower than Combustible Cigarettes



The abuse liability of Ploom[®] System is likely lower than Combustible Cigarettes

- Nicotine exposure is lower than combustible cigarettes
- Adults who smoke like their usual brand combustible cigarettes more than Ploom[®] System
- Many adults who smoke switch completely to Ploom[®] System or reduce consumption of combustible cigarettes by $\geq 50\%$
- Substantially lower levels of HPHCs compared to combustible cigarettes



NICOTINE EXPOSURE

Pharmacokinetics (PK)



SUBJECTIVE EFFECTS

Pharmacodynamics (PD), Product Liking, Satisfaction, Craving, Withdrawal



USE PATTERNS

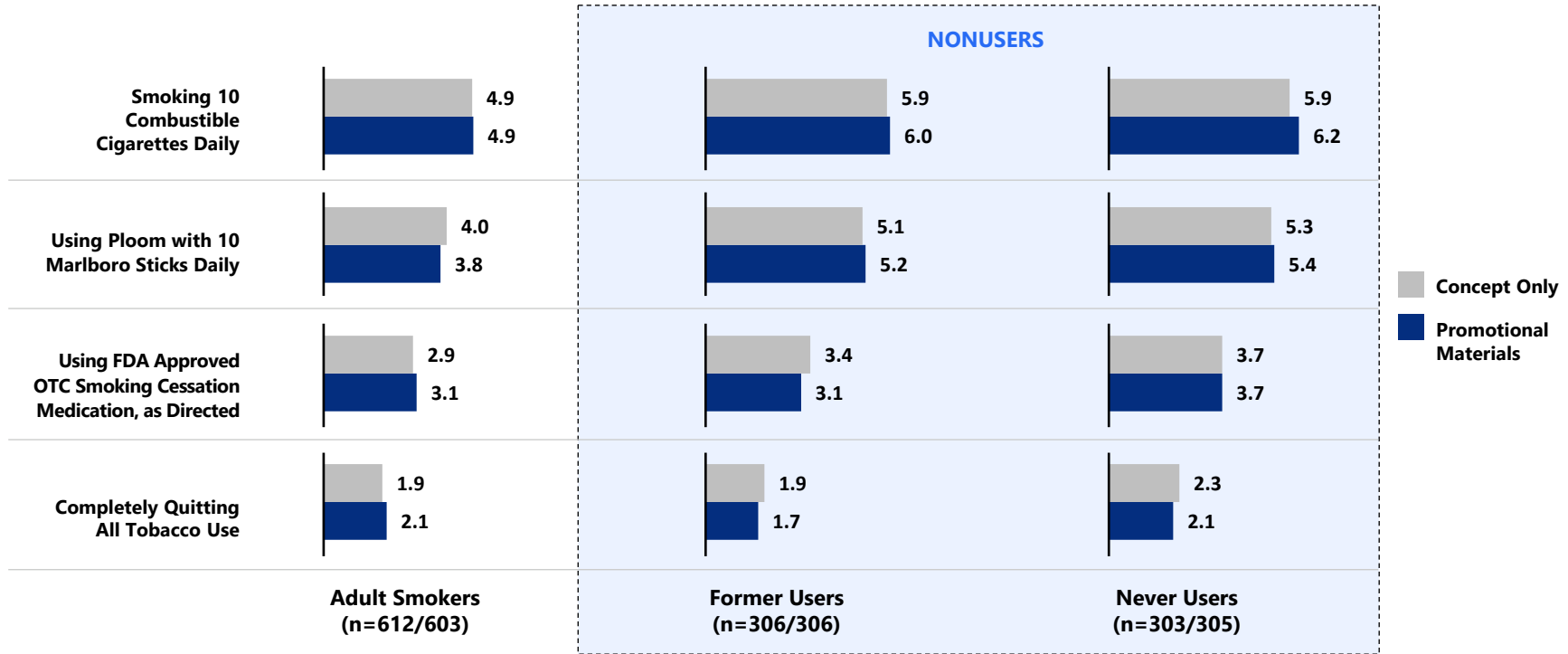
Actual Use



HEALTH RISK ASSESSMENT

Chemical Analyses, BOE Study

Ploom® System Perceived Less Risky Than Smoking Cigarettes and More Risky Than Using NRTs And Quitting All Tobacco



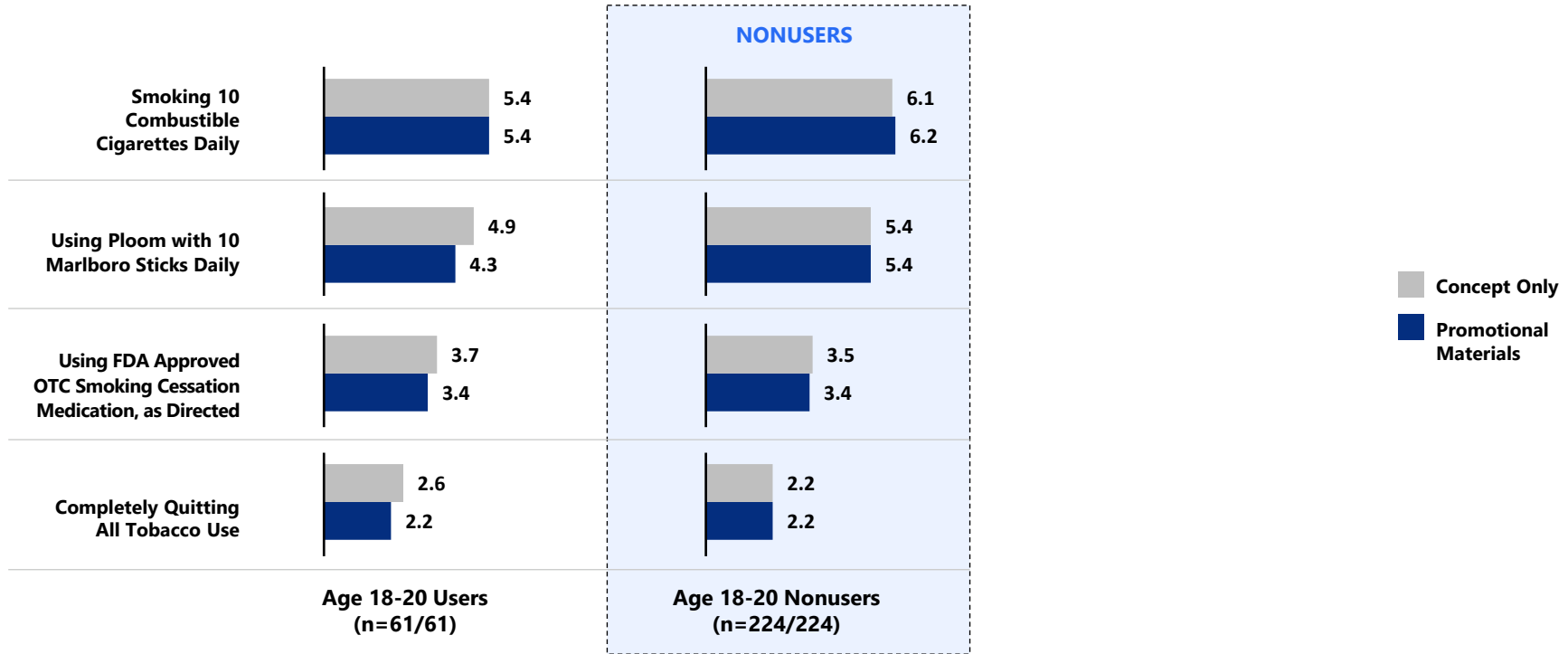
Source: PBICC Study Technical Report, Tables 173-174.

Altria Client Services & JTI Group | Next Generation Nicotine Delivery | June 2025

Horizon Innovations LLC is a joint venture between Philip Morris USA Inc. and JTI (US) Holding Inc. for the commercialization of Ploom® in the U.S. market.



Ploom® System Perceived Less Risky Than Smoking Cigarettes and More Risky Than Using NRTs And Quitting All Tobacco



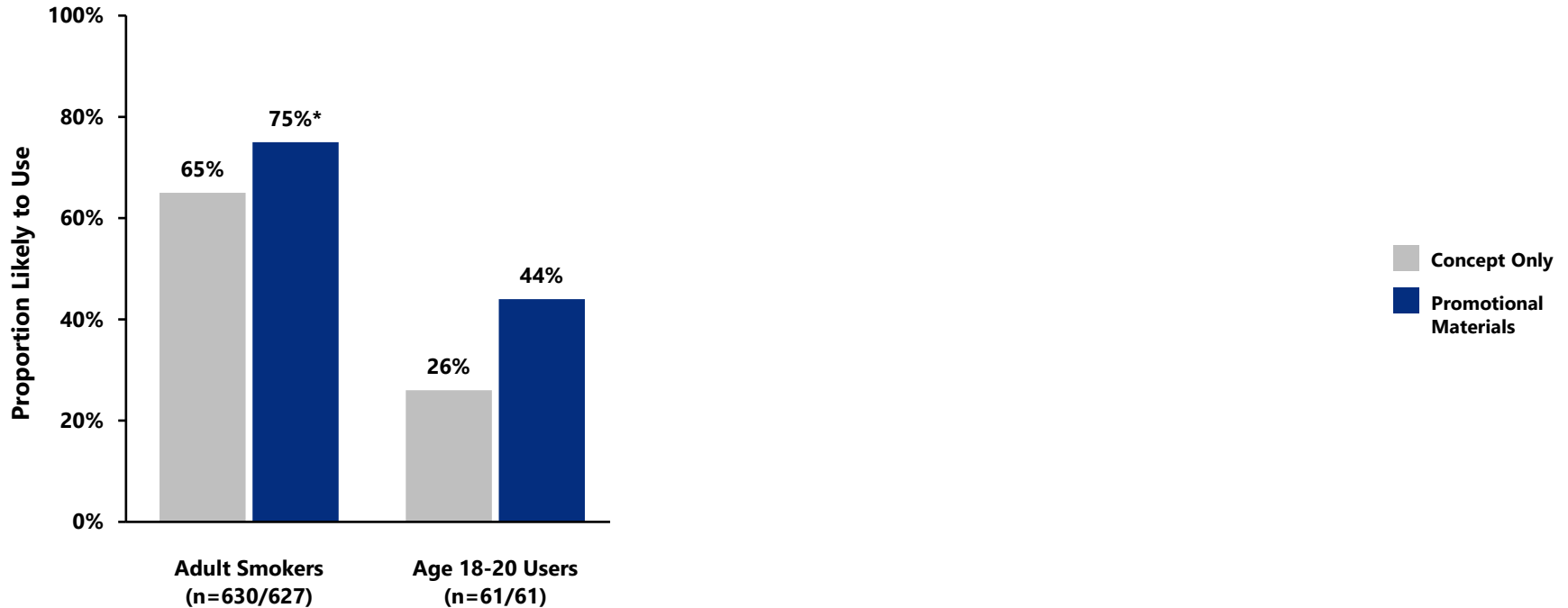
Source: PBICC Study Technical Report, Table 173.

Altria Client Services & JTI Group | Next Generation Nicotine Delivery | June 2025

Horizon Innovations LLC is a joint venture between Philip Morris USA Inc. and JTI (US) Holding Inc. for the commercialization of Ploom® in the U.S. market.



Majority of Legal Aged Adult Smokers and Minority of Age 18-20 Tobacco Users Classified as Likely to Use Ploom[®] System



* Indicates statistically significant at $p < 0.05$

Likely to use the Ploom[®] System was based on an intention composite score > 3.5 and answered "Yes" to the purchase intent question.

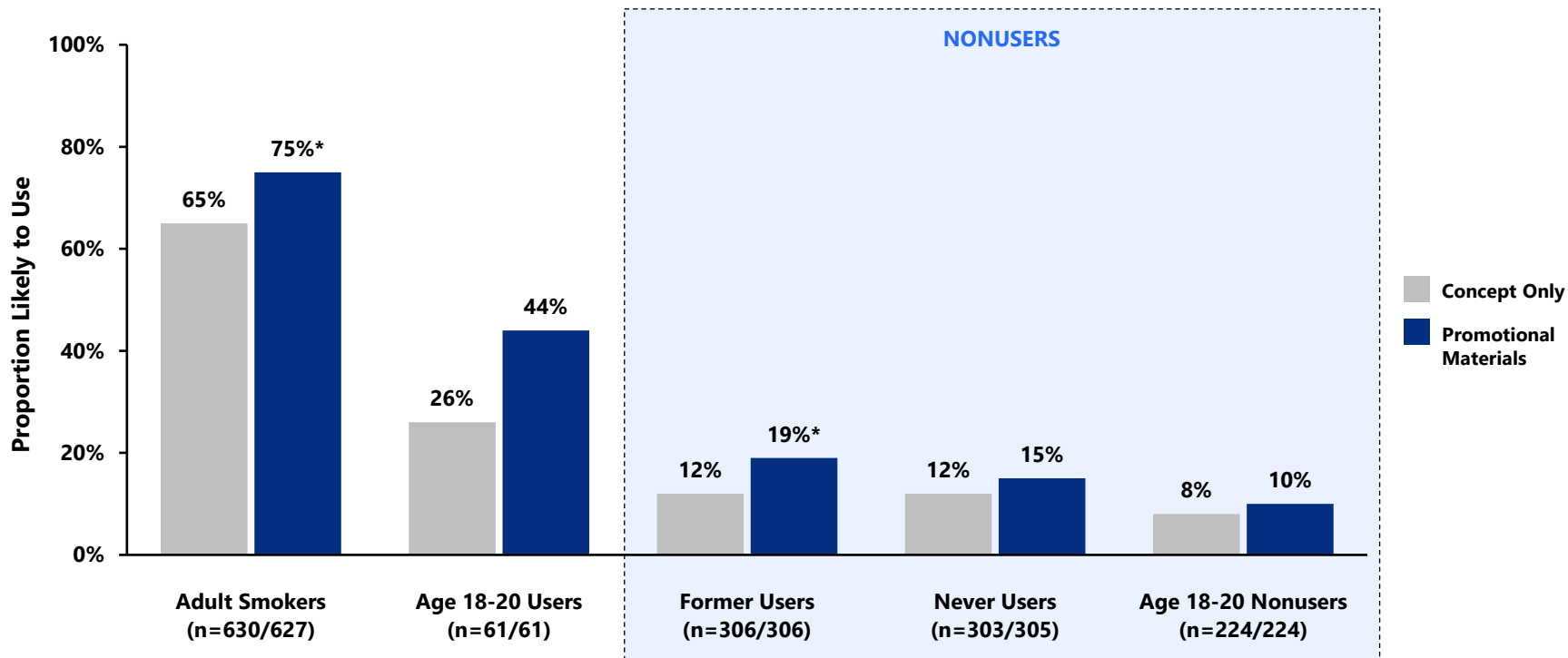
Source: PBICC Study Technical Report, Table 30.

Altria Client Services & JTI Group | Next Generation Nicotine Delivery | June 2025

Horizon Innovations LLC is a joint venture between Philip Morris USA Inc. and JTI (US) Holding Inc. for the commercialization of Ploom[®] in the U.S. market.



Low Likelihood of Use Among Adult Nonusers of Tobacco Products



* Indicates statistically significant at $p < 0.05$
 Likely to use the Ploom® System was based on an intention composite score > 3.5 and answered "Yes" to the purchase intent question.
 Source: PBICC Study Technical Report, Table 30.

Integration of Multiple Lines of Evidence to Demonstrate APPH

- ✓ **HPHC substantially reduced**
- ✓ **Switching will reduce exposure to most HPHCs which is reasonably likely to reduce smoking-related disease risks**
- ✓ **Many adults who smoke switch completely or reduce consumption of combustible cigarettes by $\geq 50\%$**
- ✓ **Abuse liability is likely lower than combustible cigarettes**
- ✓ **Adult tobacco users perceive products less risky than combustible cigarettes, but not risk-free**
- ✓ **Low likelihood of use among nonusers, including youth**

Net Population Benefit



APPH

Appropriate for the Protection of Public Health

CPD=cigarettes per day; HPHC=harmful and potentially harmful constituents.

Altria Client Services & JTI Group | Next Generation Nicotine Delivery | June 2025

Horizon Innovations LLC is a joint venture between Philip Morris USA Inc. and JTI (US) Holding Inc. for the commercialization of Ploom® in the U.S. market.

Any questions?

