Advancing Harm Reduction for Adults Who Smoke

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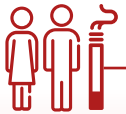
Scientific Strategy and Advocacy

Altria

FAMILY OF COMPANIES

The Problem: Harm Caused from Cigarette Smoking

COMBUSTIBLE TOBACCO – MOST HAZARDOUS FORM OF TOBACCO



~31 MILLION[1]
U.S. adult smokers

→ **OVERWHELMING EVIDENCE** →

Cigarette smoking is addictive and causes serious diseases including:

Lung cancer | Emphysema | Cardiovascular disease

~480,000 U.S. Deaths
Attributable Each Year to Cigarette Smoking[2]

[1] Source: Altria Client Services LLC Adult Tobacco Consumer Tracker (ALCS ATCT) – Q1, 2024.
[2] https://www.cdc.gov/tobacco/campaign/tips/resources/data/cigarette-smoking-in-united-states.html#:~:text=Cigarette%20smoking%20remains%20the%20leading,than%20480%2C000%20Americans%20each%20year.

Tobacco Harm Reduction Framework

Traditional Strategies

Decrease Initiation + Increase Cessation

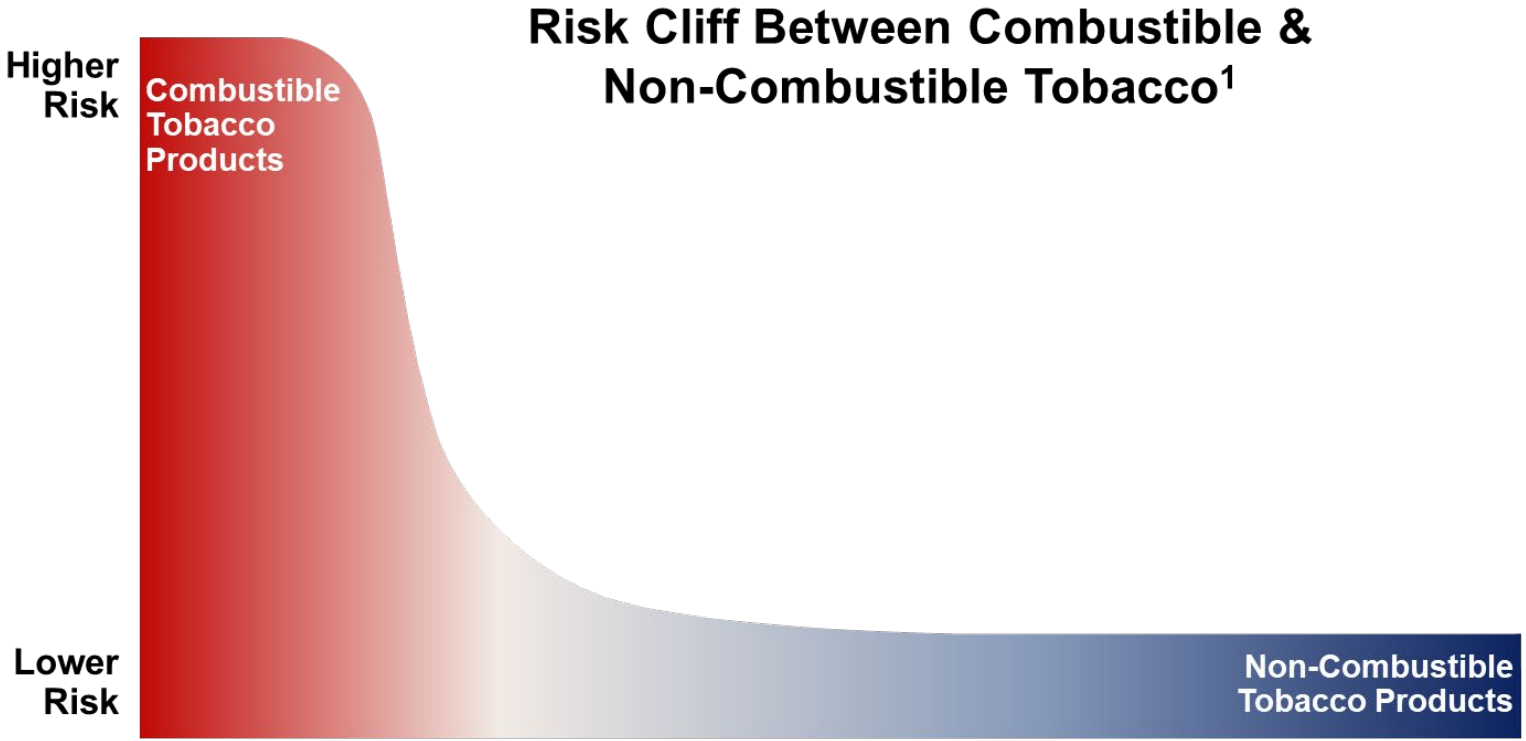
Complement to Existing Approach

Switching ATC to Less Harmful Products = Accelerate Smoking-Related Harm Reduction

Tobacco Harm Reduction Framework

ATC=Adult Tobacco Consumers

Tobacco Harm Reduction Focuses on Moving Adults Who Smoke Down the "Risk Cliff"



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

A Portfolio Approach to Harm Reduction

Advance Altria's harm reduction aspiration through smoke-free product platforms

Smokeless Tobacco Products

e.g., Copenhagen®

Modern Oral Tobacco Products

e.g., *on!*® Nicotine Pouches

Heated Tobacco Products

e.g., PLOOM®*

E-Vapor Products

e.g., NJOY®

*PLOOM® is currently unavailable for sale in the United States.

Scientific Framework

CONSTITUENT REDUCTION

Product Design and Control | **Chemical and Physical Characterization**

THE PRODUCT

- Chemistry Manufacturing and Controls
- Product Stability
- Chemical characterization

INDIVIDUAL RISK REDUCTION

Toxicology and Risk Assessment | **Studies in Adult Human Subjects**

EXPOSURE and HEALTH RISK

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

POPULATION HARM REDUCTION

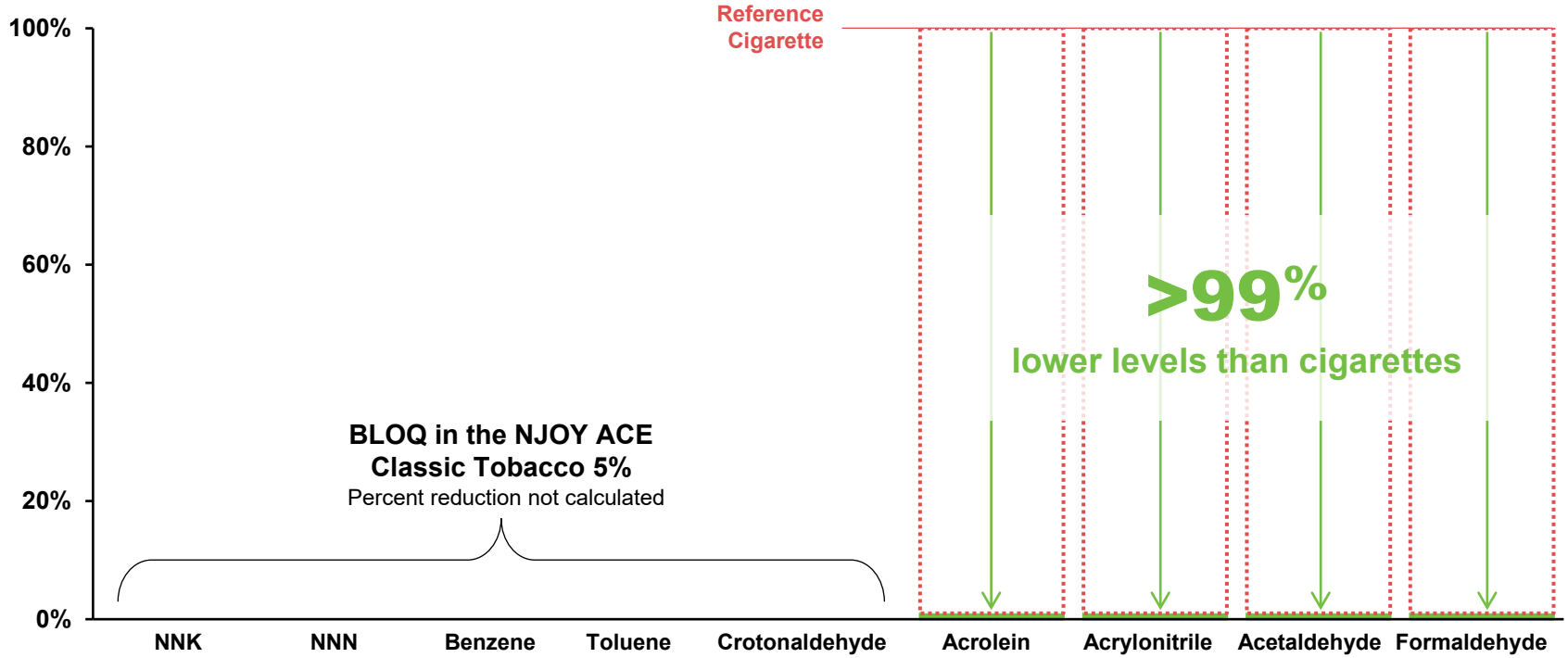
Perception and Behavior Assessment | **Risks and Benefits to Health of the Population**

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

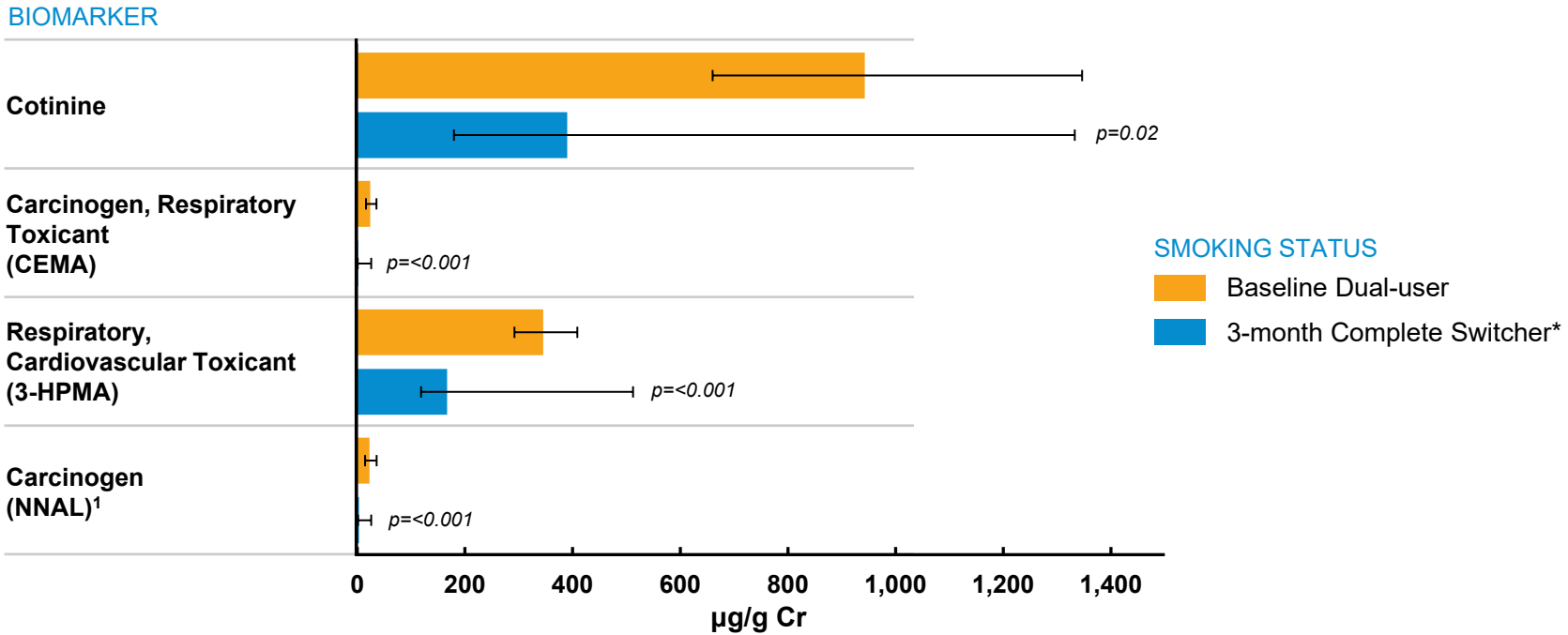
HPHCs in NJOY ACE® Classic Tobacco 5% are Not Detected or Substantially Reduced Compared to Cigarettes

CONSTITUENT REDUCTION



BLOQ=below limit of quantification; HPHC=harmful and potentially harmful constituents; NNK=4-(methylnitrosamino)-1-(3-pyridyl)-1-butanone; NNN=N-nitrosonornicotine.
Source: Percent reductions based on average HPHC levels in 5% Classic Tobacco NJOY ACE product compared to cigarette mainstream smoke levels measured under ISO conditions.

Biomarkers of Exposure are Significantly Reduced Among Switchers Based on Real World Evidence



* Indicates that biomarker levels were significantly lower than dual-users ($p < 0.05$); Data represented as Least Square Means ± 95% CI from Statistical Model.
3-HPMA=3-Hydroxypropylmercapturic Acid; CEMA=Cyanoethyl mercapturic acid; NNAL=4-(Methylnitrosamino)-1-(3-pyridyl)-1-butanol). [1]NNAL is expressed as ng/g Cr.

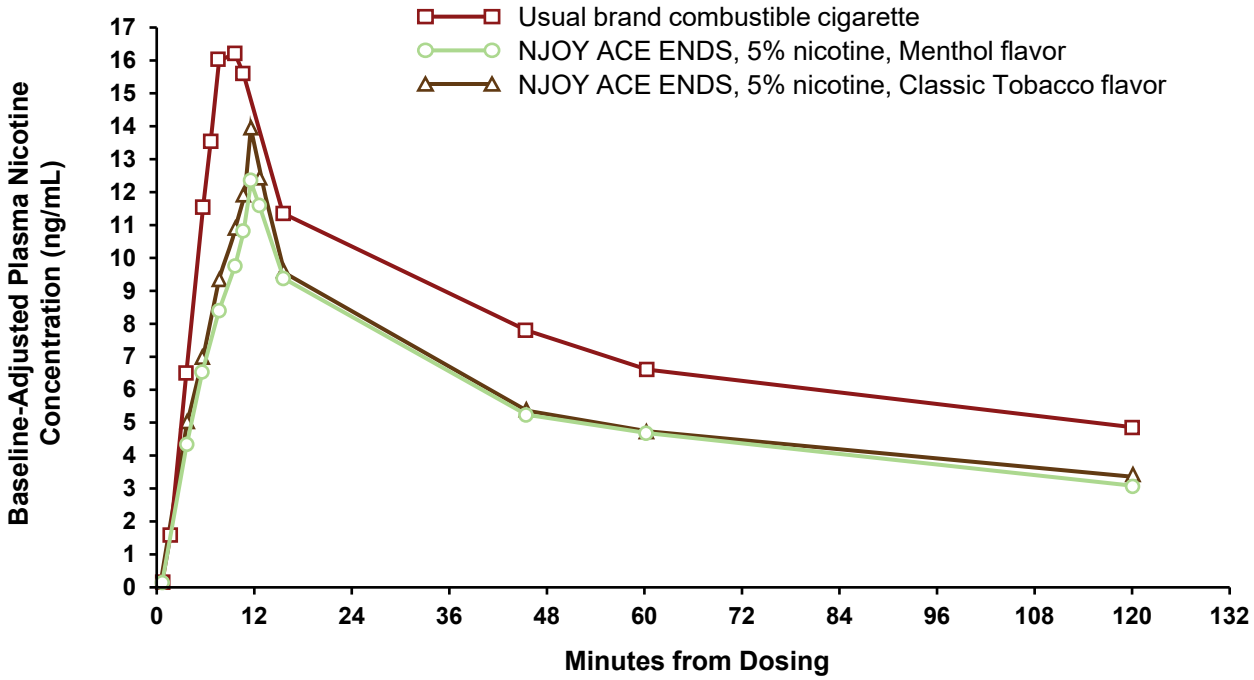
Nicotine PK indicates NJOY ACE® Abuse Liability Not Likely to be Higher Than Cigarettes

INDIVIDUAL RISK REDUCTION

Abuse Liability

"The new products' abuse liability—i.e., ability to promote continued use, addiction, or dependence—is comparable to that of combusted cigarettes and other ENDS tested"

Quotes from FDA Technical Project Lead PMTA Summary



PK=pharmacokinetics.

Longitudinal Cohort Study Demonstrates Significant Switching Potential for NJOY ACE

POPULATION HARM REDUCTION

"The NJOY User Study demonstrated that **switching from combusted cigarettes to the new ENDS products does occur among current adult smokers.**

The applicant has therefore demonstrated the potential for these products to benefit adult smokers as compared to continued exclusive cigarette use."

Quotes from FDA Technical Project Lead PMTA Summary (Emphasis added)

Longitudinal Cohort Study Overview

PROSPECTIVE LONGITUDINAL
ONLINE OBSERVATIONAL SURVEY

Evaluating the Effectiveness of NJOY ACE® ENDS on Reduction and Switching From CC Use

PURPOSE

Assesses relationship between the frequency of combustible cigarette smoking, switching from combustible cigarettes to ENDS, and the purchasing and use of NJOY ENDS products

STUDY DESIGN

National purposive sample of 8,002 US adult subjects aged 21+ years who first used NJOY ACE® within the 12-month period prior to completing the baseline survey

COHORTS

Primary Outcomes

Baseline and 3-month timepoints

Secondary Outcomes

Baseline, 3-months and 6-month time-points

CC=combustible cigarette.

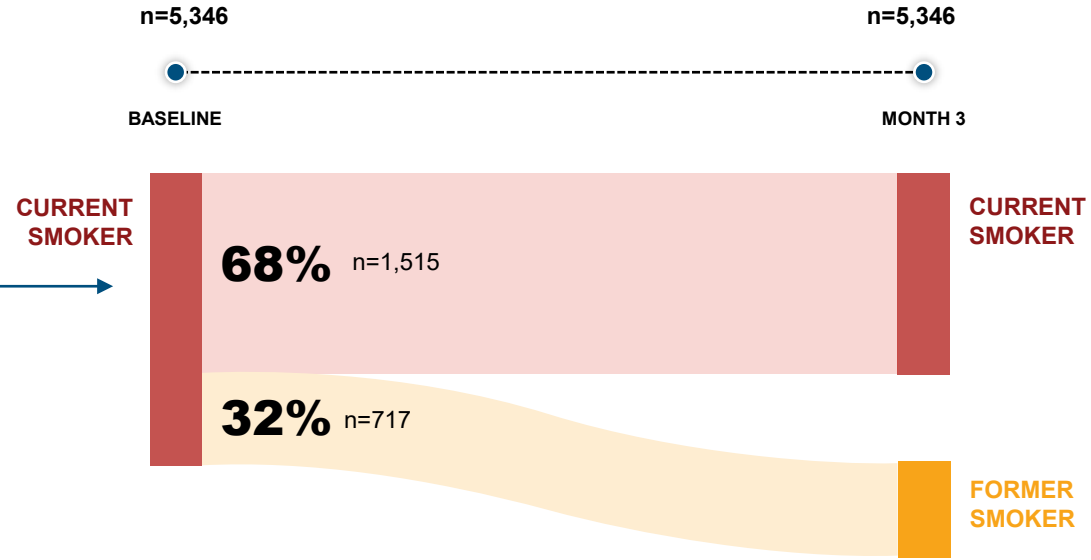
Survey Data Collected

POPULATION HARM REDUCTION

- Participant demographics
- NJOY ACE® use
- Combustible tobacco cigarette smoking behaviors
- Non-NJOY ENDS use
- Other tobacco/nicotine product use
- Harm perceptions and perceived addictiveness
- Negative consequences associated with ENDS use
- Health outcomes
  (i.e., respiratory symptoms, fatigue, physical health)

Real World Evidence Demonstrates Switching Success with NJOY ACE®

32%
of Adult Smokers
(21+ at Baseline)
transitioned to Former Smokers*

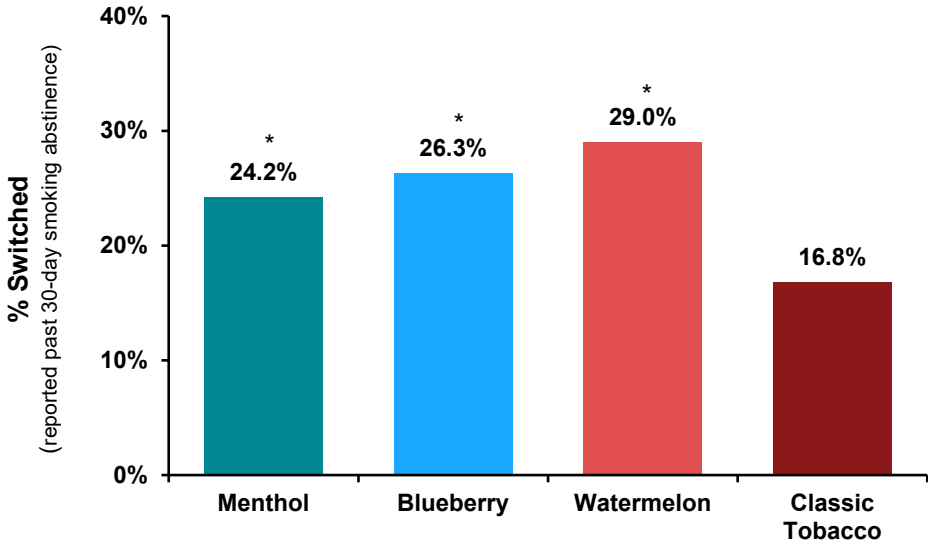


* Indicates switching rate calculated based on the number of participants initially using NJOY ACE at baseline and completing survey at three months (per protocol population).
Source: Prospective Longitudinal Cohort Study Figure 7-1.

Flavored NJOY® Products More Effective in Promoting Complete Switching Relative to Tobacco-Flavored

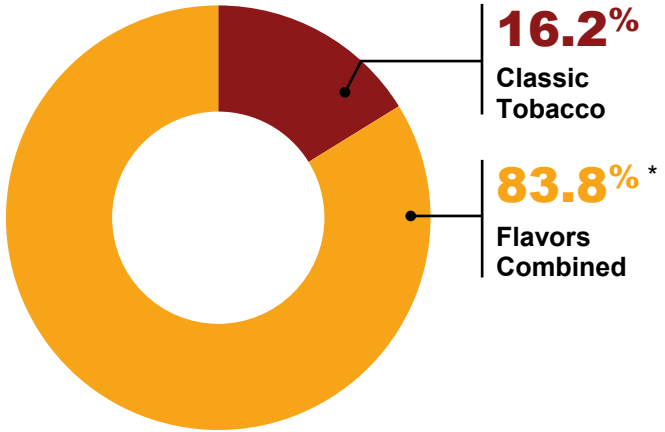
Complete Switching at 3 Months

(based on those completing the survey at 3 months)



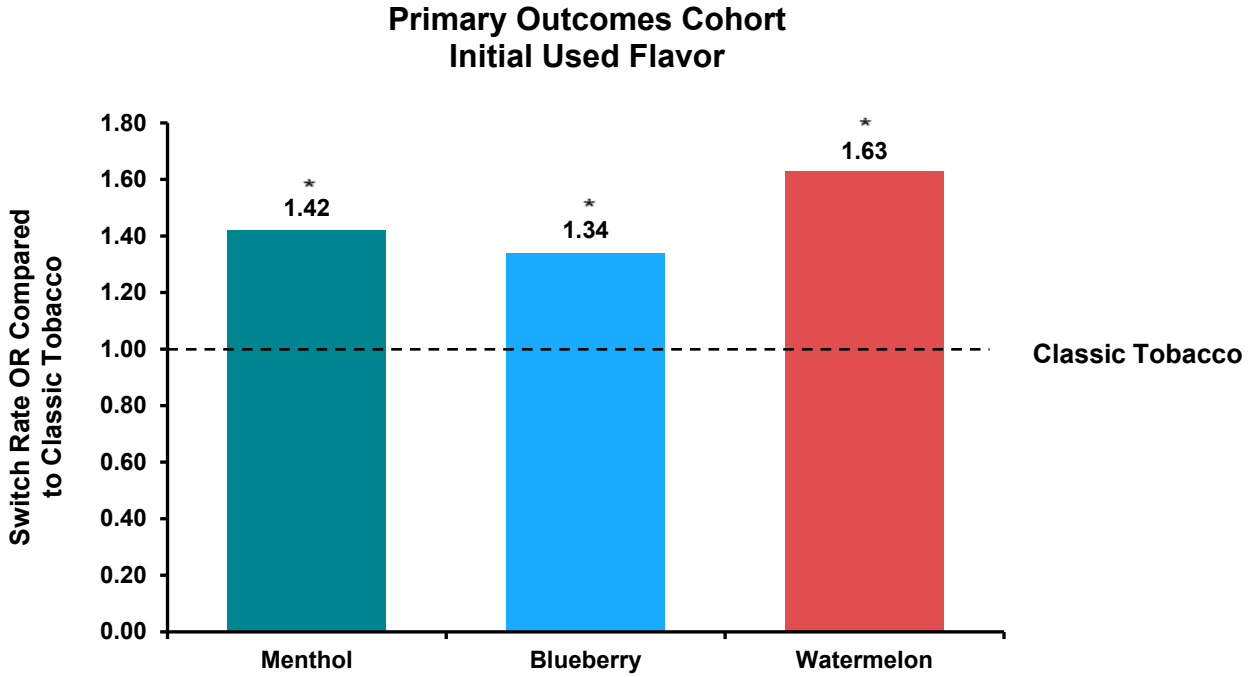
Proportion of Complete Switchers at 3 Months

(based on those completing the survey at 3 months)



*Statistically significantly greater than Classic Tobacco-flavored NJOY ACE products
Analysis shows per protocol 30-day point prevalence abstinence for initially used NJOY ACE flavor.
Source: NJOY ACE User Survey Supplemental Blueberry and Watermelon Report; Initial Used NJOY Flavor.

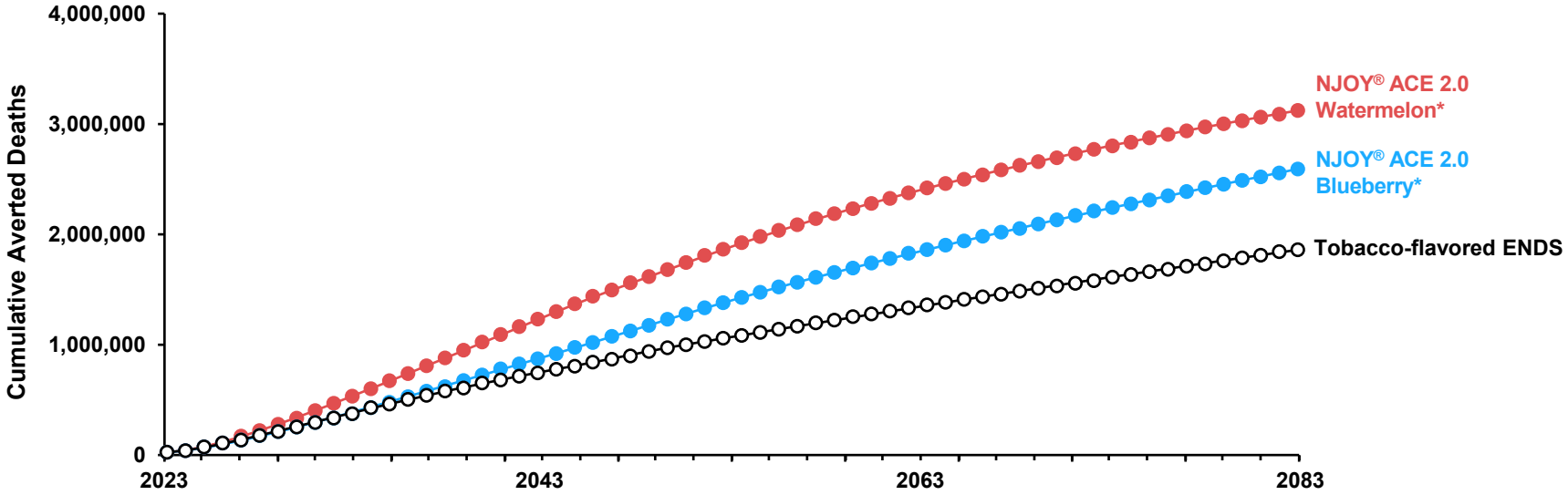
Higher Odds of Complete Switching for NJOY ACE® Flavors vs. NJOY ACE® Classic Tobacco



*Statistically significantly greater than Classic Tobacco-flavored NJOY ACE products
Source: NJOY ACE User Survey Supplemental Menthol Report; NJOY ACE User Survey Supplemental Blueberry and Watermelon Report; Analysis shows Switch Rate Adjusted Odds Ratios for Per Protocol 30-Day Point Prevalence Abstinence for Initially Used NJOY ACE Flavor

Population Impact Model

Cumulative Averted Deaths (SADs – SVADs) for ENDS Scenarios vs. No-ENDS Scenario for the Total Population from 2023-2083



* Per protocol
Source: Module 6.6.1 PopModel – ACE 2.0 BLE – Report Figure 5.2.
ENDS= electronic nicotine delivery system; SAD=smoking-attributable death; SVAD=smoking and vaping-attributable death.

NJOY ACE® ENDS Youth Prevalence is rare

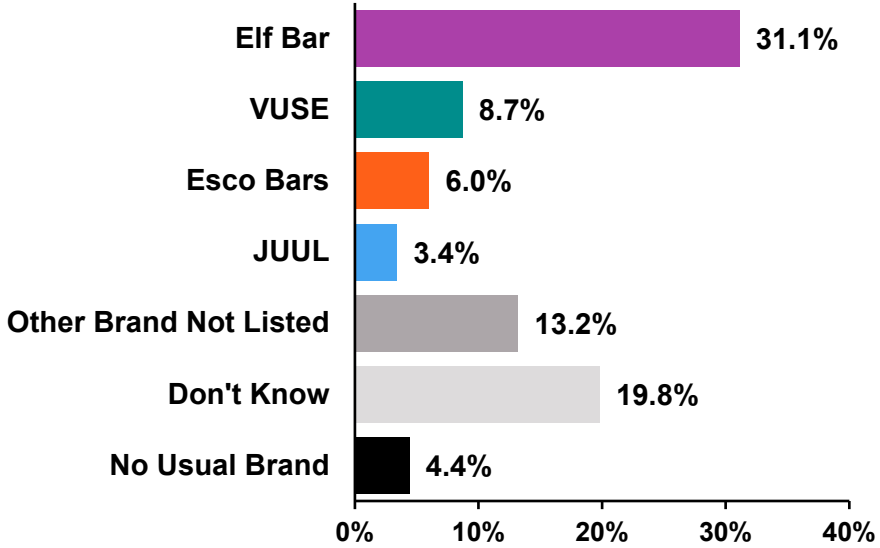
NJOY Brand Detection Trends in NYTS

NYTS	NJOY Usual Brand Used Among Middle and High School E-Cigarette Users	Last 30-Day ENDS Use % (95% CI)
2021	NA[a]	11.3 (9.7–13.0)
2022	NA[a]	14.1 (12.4–16.0)
2023	NA[a]	10.0 (8.8–11.4)

[a]Data not shown because responses were too low to determine statistically reliable estimates

Sources: Cullen et al., 2019; Wang et al., 2020; Park-Lee et al., 2021; Cooper et al., 2022; Birdsey et al., 2023
NYTS=National Youth Tobacco Survey; CI=confidence interval; ENDS=electronic nicotine delivery system; NA=not applicable

2023 Usual Brand Used Among Middle and High School Current E-Cigarette Users



National Youth Tobacco Survey, 2023. MMWR Morb Mortal Wkly Rep 2023;72:1173–1182. DOI: http://dx.doi.org/10.15585/mmwr.mm7244a1

FDA Technical Project Lead Highlights

FDA U.S. FOOD & DRUG ADMINISTRATION

Technical Project Lead (TPL) Review of PMTAs

New Products Subject to this Review[1]	
STNs	PM0000630-PM0000631
Common Attributes	
Submission date	March 30, 2020
Receipt date	March 30, 2020
Applicant	NJOY, LLC
Product manufacturer	NJOY, LLC
Application type	Standard
Product category	ENDS (VAPES)
Product subcategory	Closed E-Cigarette
Cross-Referenced Submissions	
All new products	(b)(4)
Supporting FDA Memoranda Relied Upon in this Review	
All STNs	• Statistical Consultation finalized on May 6, 2021 • Tobacco Product Surveillance Team Consultations finalized on September 30, 2020 and on February 2, 2022 • OHCE Consultation finalized on February 24, 2022
Recommendation	
Issue marketing granted orders for the new products subject of this review.	

Technical Project Lead (TPL): Digitally signed by Luis G. Valerio -S
Date: 2022.06.09 17:27:29 -04'00'

Luis G. Valerio, Jr., Ph.D., ATS
Associate Director
Division of Nonclinical Science

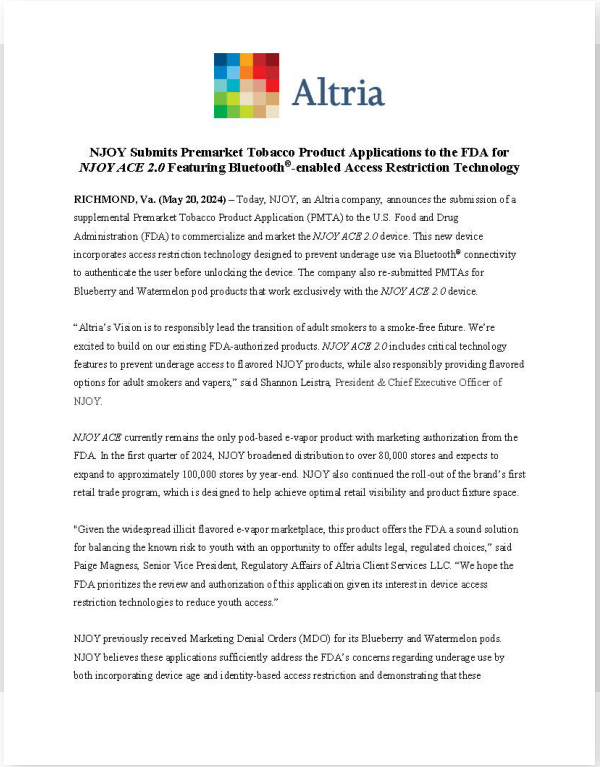
Signatory Decision: Concur with TPL recommendation and basis of recommendation

Digitally signed by Matthew R. Holman -S
Date: 2022.06.10 06:31:28 -04'00'

Matthew R. Holman, Ph.D.
Director
Office of Science

> **"Based on the information provided in the application and other scientific data, as described in this Technical Project Lead (TPL) review, I find that permitting the marketing of the new products listed above ("new products" or "subject ENDS") is appropriate for the protection of the public health (APPH)"**

NJOY Submits PMTAs to FDA for NJOY ACE® 2.0 Featuring Bluetooth®- enabled Access Restriction Technology



Altria

NJOY Submits Premarket Tobacco Product Applications to the FDA for *NJOY ACE 2.0* Featuring Bluetooth®-enabled Access Restriction Technology

RICHMOND, Va. (May 20, 2024) – Today, NJOY, an Altria company, announces the submission of a supplemental Premarket Tobacco Product Application (PMTA) to the U.S. Food and Drug Administration (FDA) to commercialize and market the *NJOY ACE 2.0* device. This new device incorporates access restriction technology designed to prevent underage use via Bluetooth® connectivity to authenticate the user before unlocking the device. The company also re-submitted PMTAs for Blueberry and Watermelon pod products that work exclusively with the *NJOY ACE 2.0* device.

"Altria's Vision is to responsibly lead the transition of adult smokers to a smoke-free future. We're excited to build on our existing FDA-authorized products. *NJOY ACE 2.0* includes critical technology features to prevent underage access to flavored NJOY products, while also responsibly providing flavored options for adult smokers and vapers," said Shannon Leistra, President & Chief Executive Officer of NJOY.

NJOY ACE currently remains the only pod-based e-vapor product with marketing authorization from the FDA. In the first quarter of 2024, NJOY broadened distribution to over 80,000 stores and expects to expand to approximately 100,000 stores by year-end. NJOY also continued the roll-out of the brand's first retail trade program, which is designed to help achieve optimal retail visibility and product fixture space.

"Given the widespread illicit flavored e-vapor marketplace, this product offers the FDA a sound solution for balancing the known risk to youth with an opportunity to offer adults legal, regulated choices," said Paige Magness, Senior Vice President, Regulatory Affairs of Altria Client Services LLC. "We hope the FDA prioritizes the review and authorization of this application given its interest in device access restriction technologies to reduce youth access."

NJOY previously received Marketing Denial Orders (MDO) for its Blueberry and Watermelon pods. NJOY believes these applications sufficiently address the FDA's concerns regarding underage use by both incorporating device age and identity-based access restriction and demonstrating that these

> **Altria's Vision is to responsibly lead the transition of adult smokers to a smoke-free future. We're excited to build on our existing FDA-authorized products.** *NJOY ACE 2.0* includes critical technology features to prevent underage access to flavored NJOY products, while also responsibly providing flavored options for adult smokers and vapers

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