

# Menthol, Blueberry, and Watermelon NJOY ACE Promote Significantly Greater Complete Switching Compared to Tobacco-flavored NJOY ACE®

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# NJOY ACE® Portfolio

## Marketing Granted Order



April 26, 2022



June 21, 2024

## Pending PMTA Review



NJOY ACE 2.0 Products include device access restrictions



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# FDA Technical Project Lead Highlights

“ ...the NJOY User Study and published literature **demonstrated that switching from combusted cigarettes to ENDS does occur among current adult smokers**. The applicant has therefore demonstrated the potential for these products to benefit adult smokers who switch completely or significantly reduce their cigarette consumption as compared to continued exclusive cigarette use.

”

“ ...the FDA determined there was sufficient evidence to demonstrate that permitting marketing of the products would be **appropriate for the protection of the public health**...

Specifically, evidence submitted by the applicant showed that these menthol-flavored products **provided a benefit** for adults who smoke cigarettes relative to that of the applicant's previously authorized tobacco-flavored products—in terms of complete switching—that is sufficient to **outweigh the risks** of the product, including youth appeal.

”

# 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





# Longitudinal Cohort Study Demonstrates Significant Switching Potential for NJOY ACE®



## NJOY User Study

“

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)

ENDS=electronic nicotine delivery system.



# Longitudinal Cohort Study Overview



POPULATION HARM REDUCTION

## 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 Cohort

Baseline and 3-month timepoints

### Secondary Outcomes Cohort

Baseline, 3-month and 6-month timepoints

\*When the study began in 2019, the following NJOY ACE products were available: NJOY ACE Classic Tobacco 2.4% and 5%, Rich Tobacco 5%, Menthol 2.4% and 5%, Blueberry 2.4% and 5%, Watermelon 2.4% and 5%. The NJOY ACE Blueberry and Watermelon products were removed from the market pursuant to the FDA Enforcement announced in January 2020.  
CC=combustible cigarette; ENDS=electronic nicotine delivery system.



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# Survey Data Collected



POPULATION HARM REDUCTION

- ✓ Participant demographics
- ✓ NJOY ACE<sup>®</sup> 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  
(e.g., respiratory symptoms, fatigue, physical health)

ENDS=electronic nicotine delivery system.



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# Sample Flow Chart

**Baseline n= 8,002\***

## PRIMARY OUTCOMES COHORT

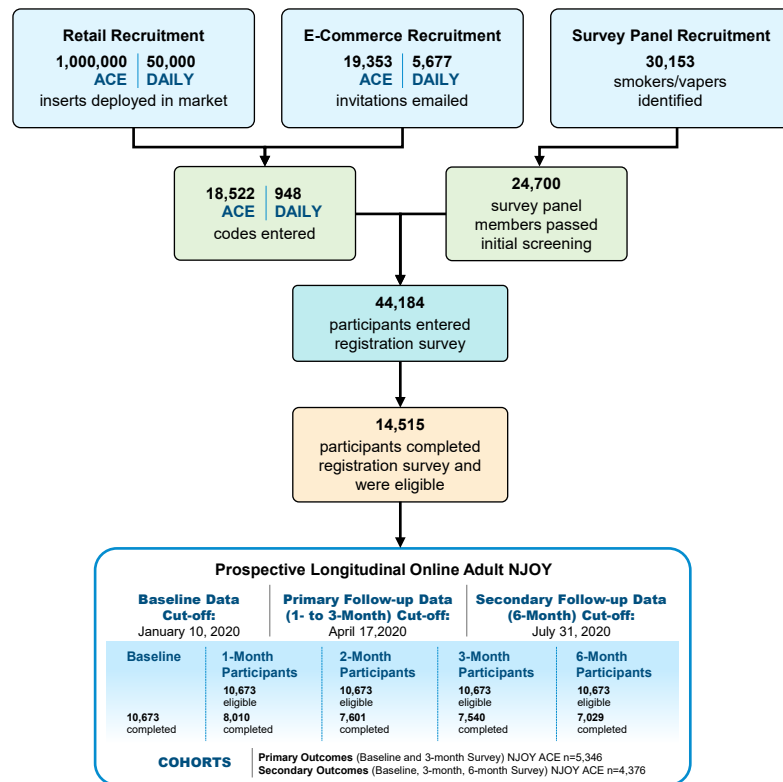
Baseline and 3-month Survey  
NJOY ACE and/or DAILY n=7540

- NJOY ACE n=5,346
- Included those that used ACE only and ACE & DAILY

## SECONDARY OUTCOMES COHORT

Baseline, 3-month, 6-month Survey  
NJOY ACE and/or DAILY n=7,029

- NJOY ACE n=4,376
- Included those that used ACE only and ACE & DAILY



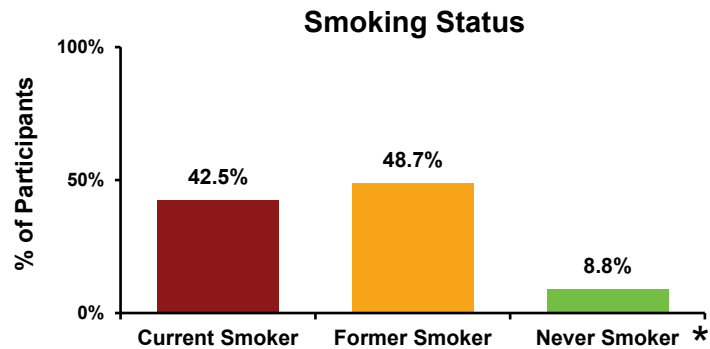
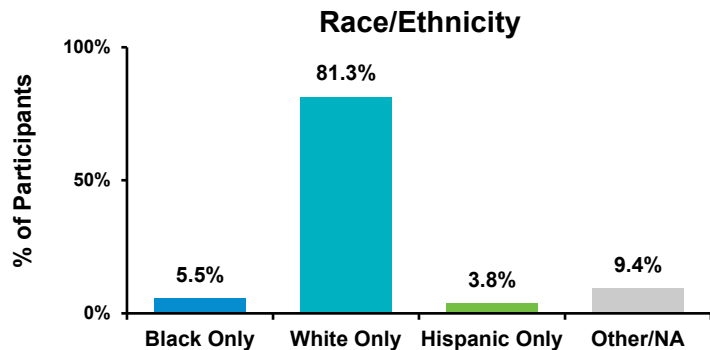
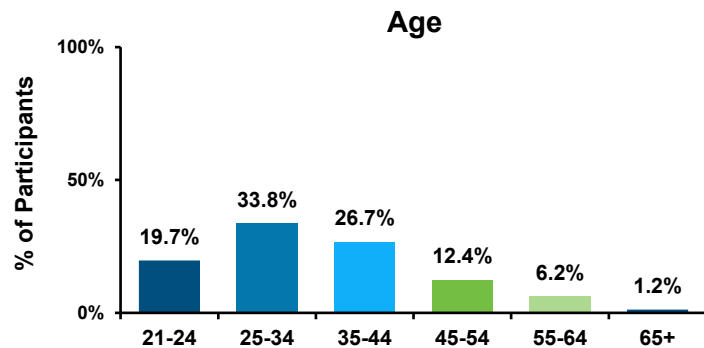
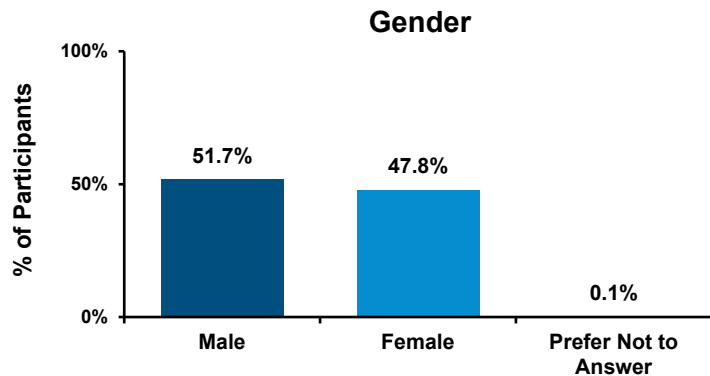


# Sample Demographics and Baseline Smoking Status



POPULATION HARM REDUCTION

Baseline n=8,002



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\* Never Smokers could be other tobacco product users  
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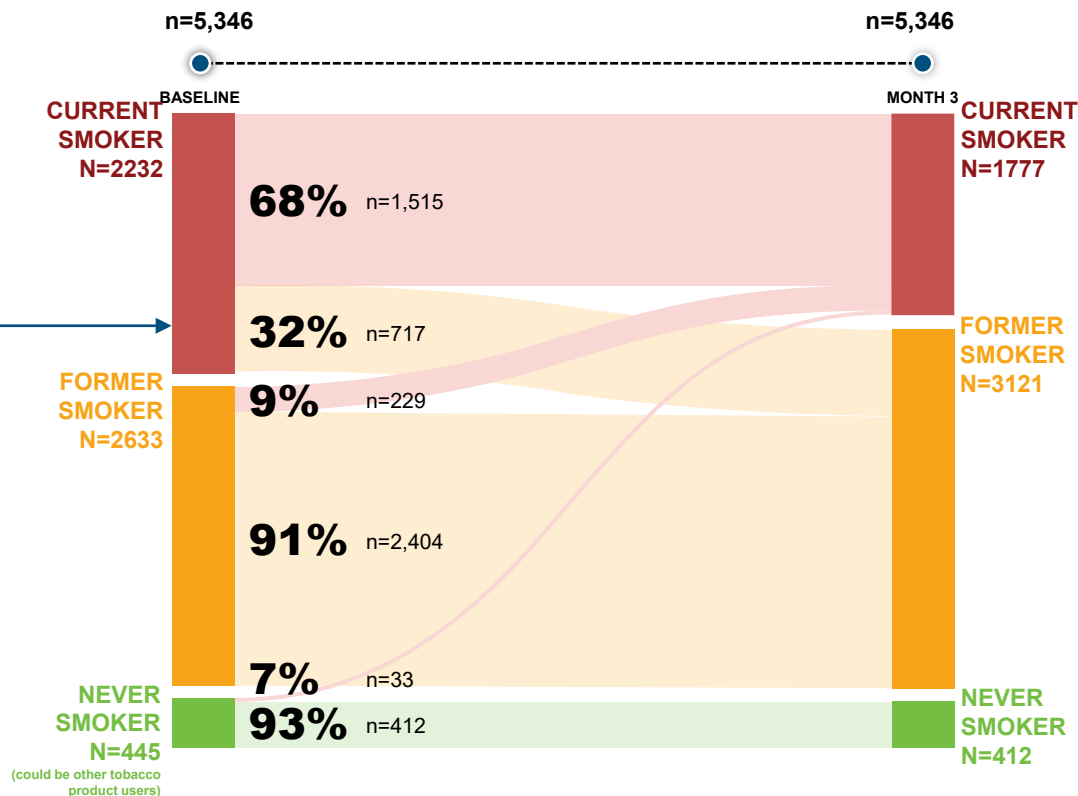
# Real World Evidence Demonstrates Switching Success with NJOY ACE® (PPA)



POPULATION HARM REDUCTION

PRIMARY OUTCOMES COHORT

**32%**  
of Adult Smokers  
(21+ at Baseline)  
transitioned to Former Smokers  
by the primary outcomes  
time point\*



\* Indicates that 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. N=36 did not answer the smoking frequency question at the Primary Outcomes time point and are not included on this figure.



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# Switching Outcomes

**Flavor-specific switch outcomes were provided by Flavor Variable, which are defined as follows:**

## Initial Used Flavor

The first NJOY ACE flavor used as reported at baseline

## Most Used Flavor at Baseline

The flavor the participant reported most using at baseline

## Flavor at the Time of Switching

The flavor the participant reported using most-often at the first follow-up time point in which they reported past 30-day point prevalence abstinence (PPA)

## PPA

Switch Rate Per Protocol Point Prevalence Abstinence

## PP 30dPPA

Switch Rate Per Protocol 30-day Point Prevalence Abstinence

## ITT 30dPPA

Switch Rate by Intent to Treat 30-day Point Prevalence Abstinence

## Adjusted Odds Ratios

Switch Rate OR 30dPPA  
Switch Rate OR ITT 30dPPA

Source: NJOY ACE User Survey Supplemental Blueberry and Watermelon Report



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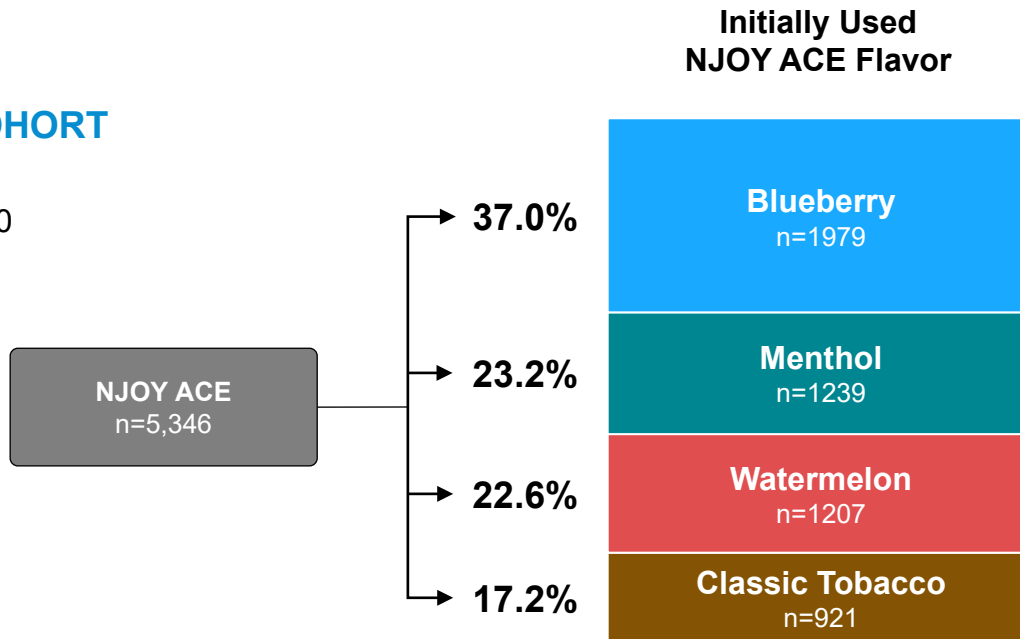
# Primary Outcomes Cohort Sample



POPULATION HARM REDUCTION

## PRIMARY OUTCOMES COHORT

Baseline and 3-month Survey  
NJOY ACE and/or DAILY n=7540

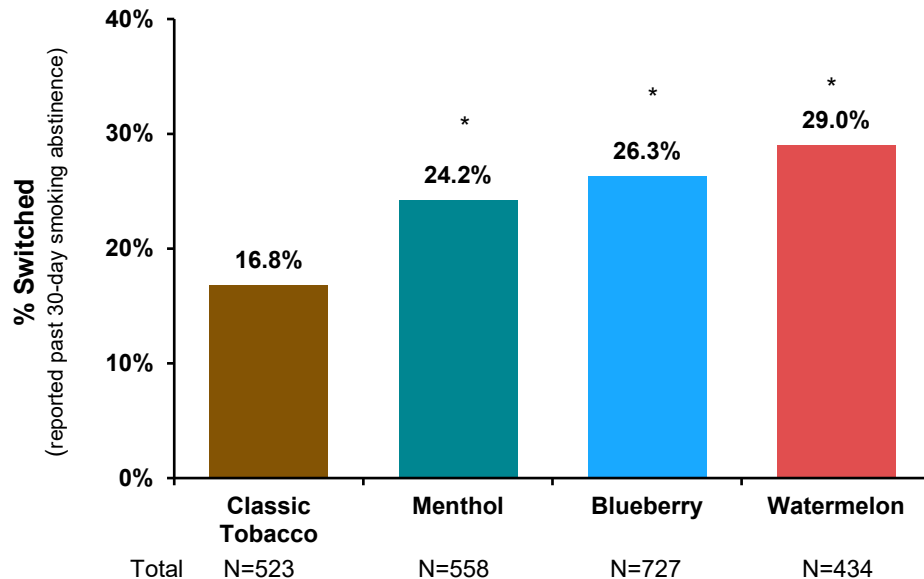




# Flavored NJOY ACE<sup>®</sup> Products More Effective in Promoting Complete Switching Relative to Tobacco-Flavored

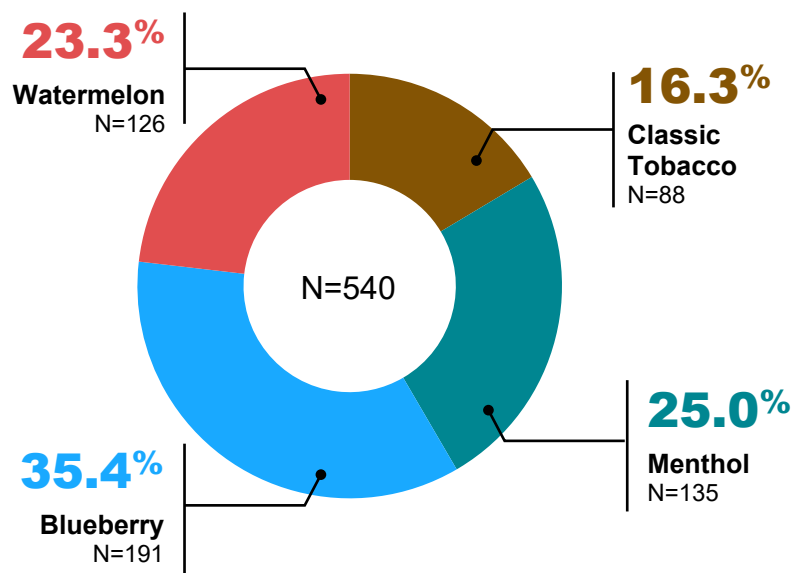
## Complete Switching at 3 Months By Initial Flavor Used

(based on those completing the survey at 3 months)



## Proportion of Complete Switchers at 3 Months By Initial Flavor Used

(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.

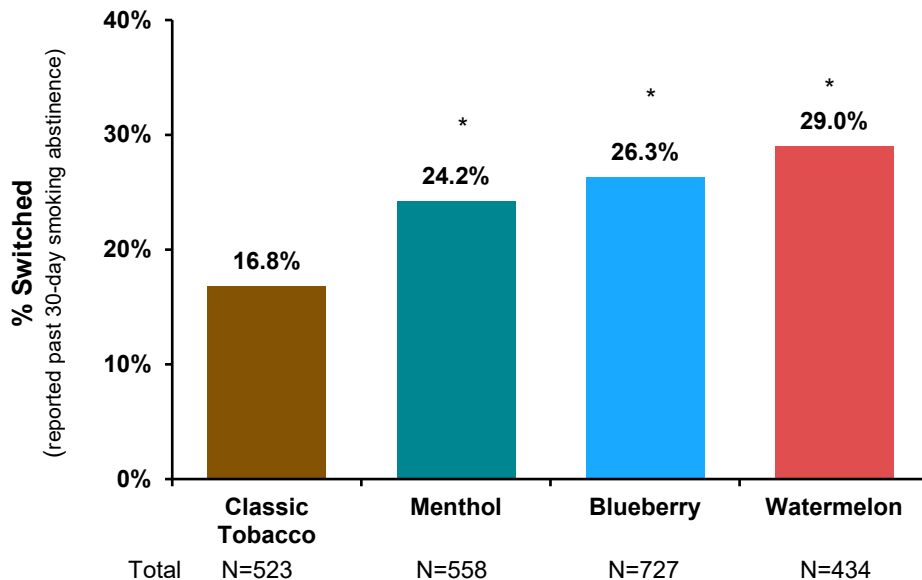




# Flavored NJOY ACE<sup>®</sup> Products More Effective in Promoting Complete Switching Relative to Tobacco-Flavored

## Complete Switching at 3 Months By Initial Flavor Used

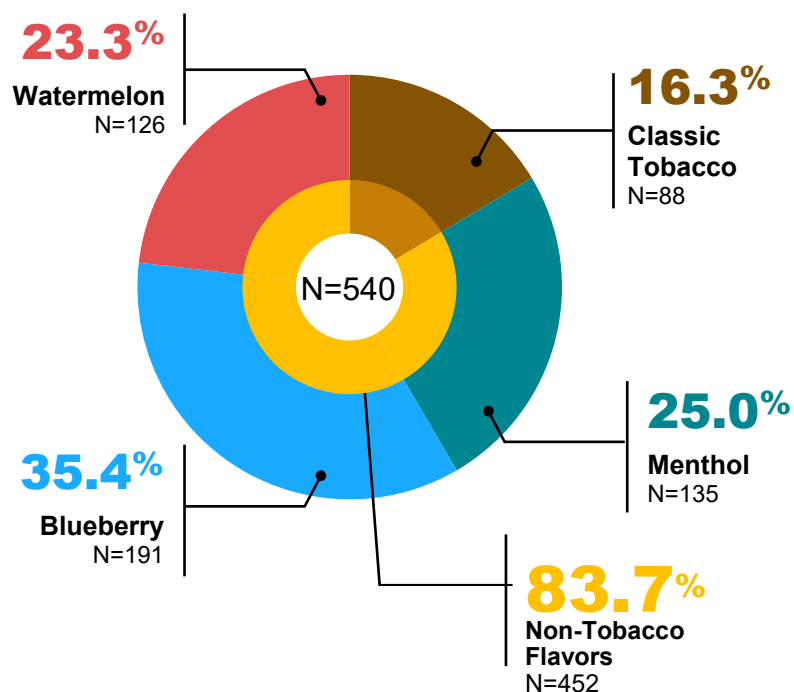
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Analysis shows per protocol 30-day point prevalence abstinence for initially used NJOY ACE flavor.  
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## Proportion of Complete Switchers at 3 Months By Initial Flavor Used

(based on those completing the survey at 3 months)





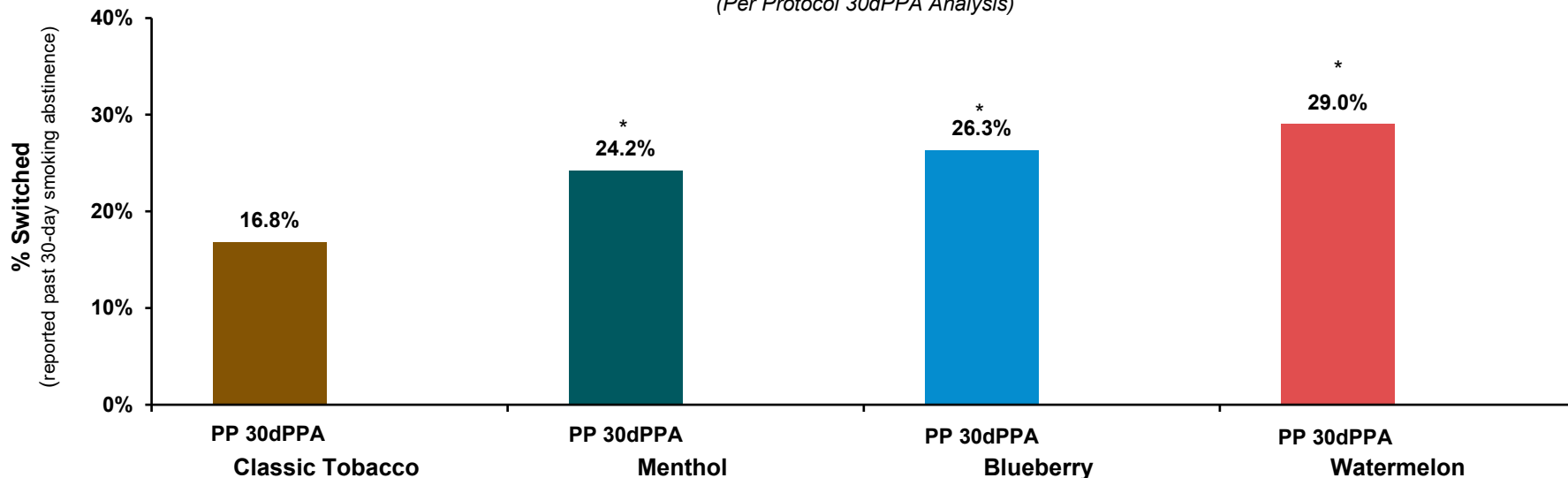
# Flavored NJOY ACE® Products Associated with Greater Complete Switching Relative to Tobacco-Flavored



POPULATION HARM REDUCTION

## Complete Switching at 3 Months By Initial Flavor Used

(Per Protocol 30dPPA Analysis)



\*Statistically significantly greater than Classic Tobacco-flavored NJOY ACE products

PPP 30dPPA, Per Protocol 30-day Point Prevalence Abstinence

Source: NJOY ACE User Survey Supplemental Blueberry and Watermelon Report; NJOY ACE User Survey Supplemental Menthol Report



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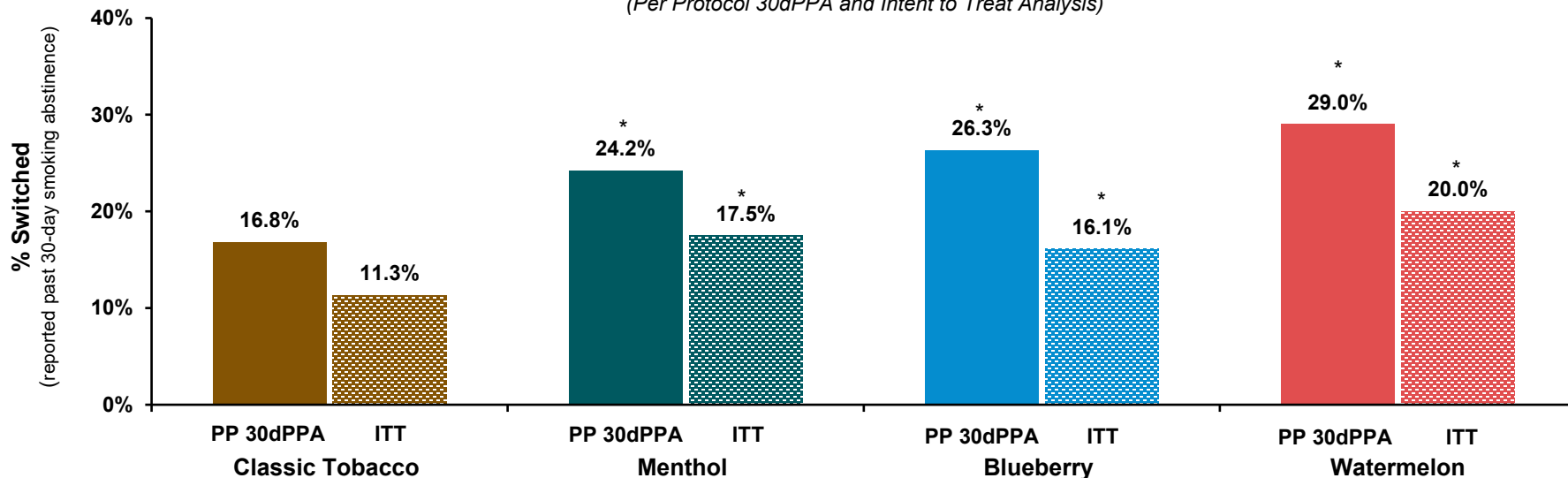
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# Flavored NJOY ACE® Products Associated with Greater Complete Switching Relative to Tobacco-Flavored

## Complete Switching at 3 Months By Initial Flavor Used

(Per Protocol 30dPPA and Intent to Treat Analysis)



\*Statistically significantly greater than Classic Tobacco-flavored NJOY ACE products  
Analysis shows ITT 30-day point prevalence abstinence for initially used NJOY ACE flavor.  
PPP 30dPPA, Per Protocol 30-day Point Prevalence Abstinence; ITT, Intent to treat.

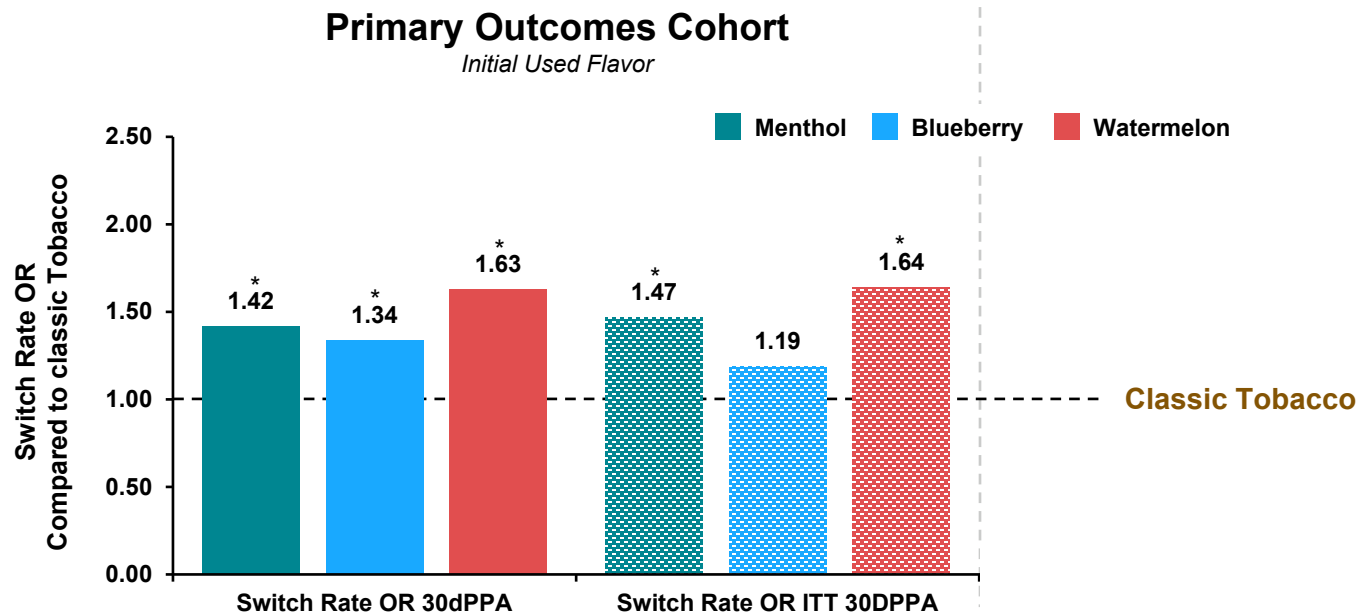
Source: NJOY ACE User Survey Supplemental Blueberry and Watermelon Report; NJOY ACE User Survey Supplemental Menthol Report







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



\*Statistically significantly greater than Classic Tobacco-flavored NJOY ACE products.

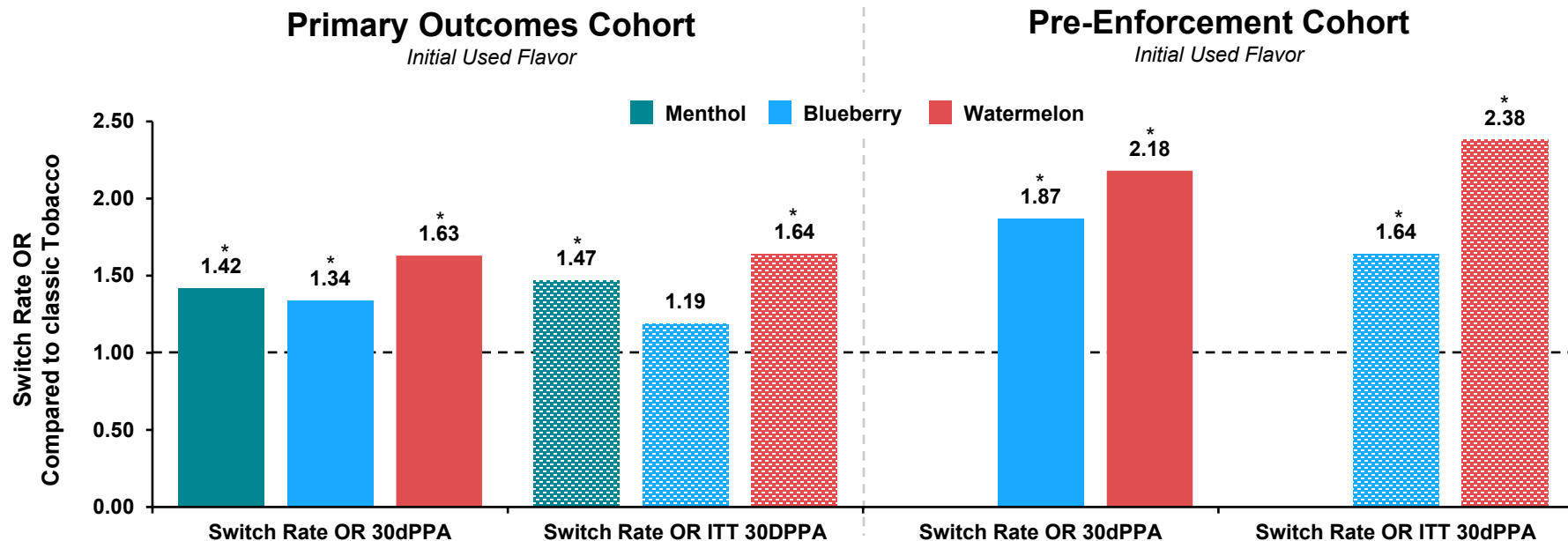
30dPPA, 30-day Point Prevalence Abstinence; ITT, Intent to treat.

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.





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



--- Classic Tobacco

\*Statistically significantly greater than Classic Tobacco-flavored NJOY ACE products.

30dPPA, 30-day Point Prevalence Abstinence; ITT, Intent to treat.

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.

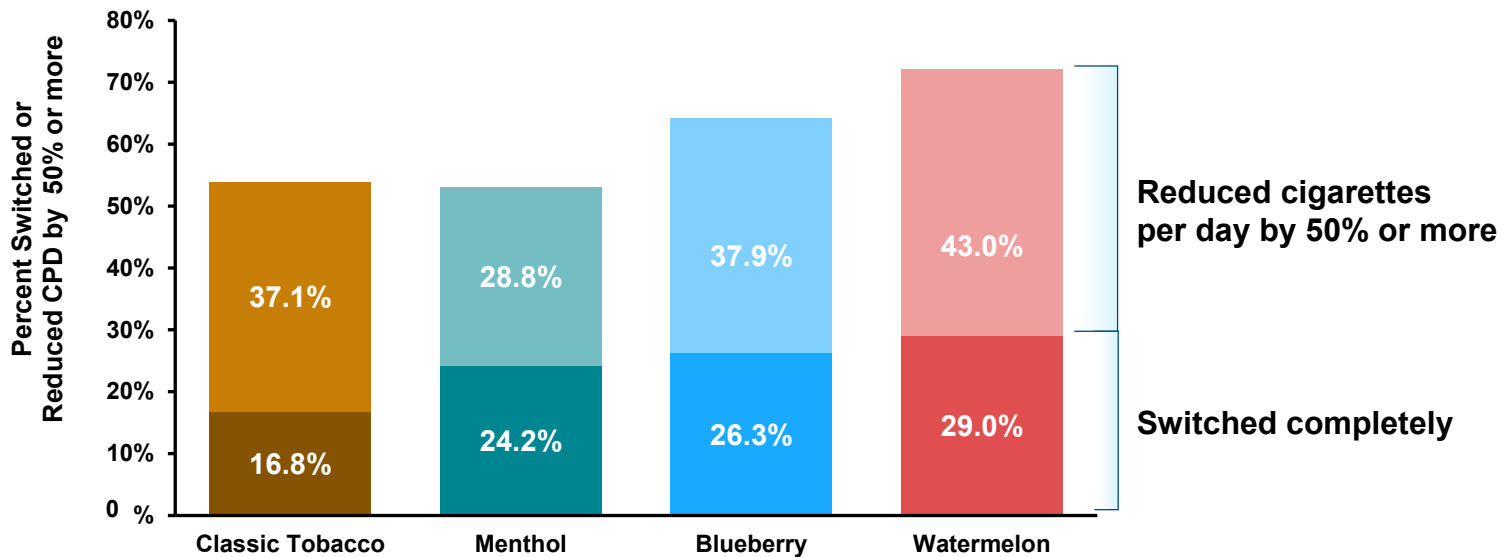


# NJOY ACE® Complete Switching and CPD Reduction at Three Months



POPULATION HARM REDUCTION

Complete Switching and CPD 50% Reduction  
by Initial Flavor Used



CPD=cigarettes per day

Source: Aggregated results include PP30dayPPA complete switch for Initial Flavor Used at 3mth timepoint, and CPD  $\geq$ 50% reduction for Initial Flavor Used at the 3mth timepoint; NJOY ACE User Survey 6mth Report.



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