

# Impact of Menthol in Switching Smokers:

Utilizing a consumer purchasing database to assess Vuse Alto Menthol



**Sarah Baxter-Wright** Vice President | US Life Sciences RAIS

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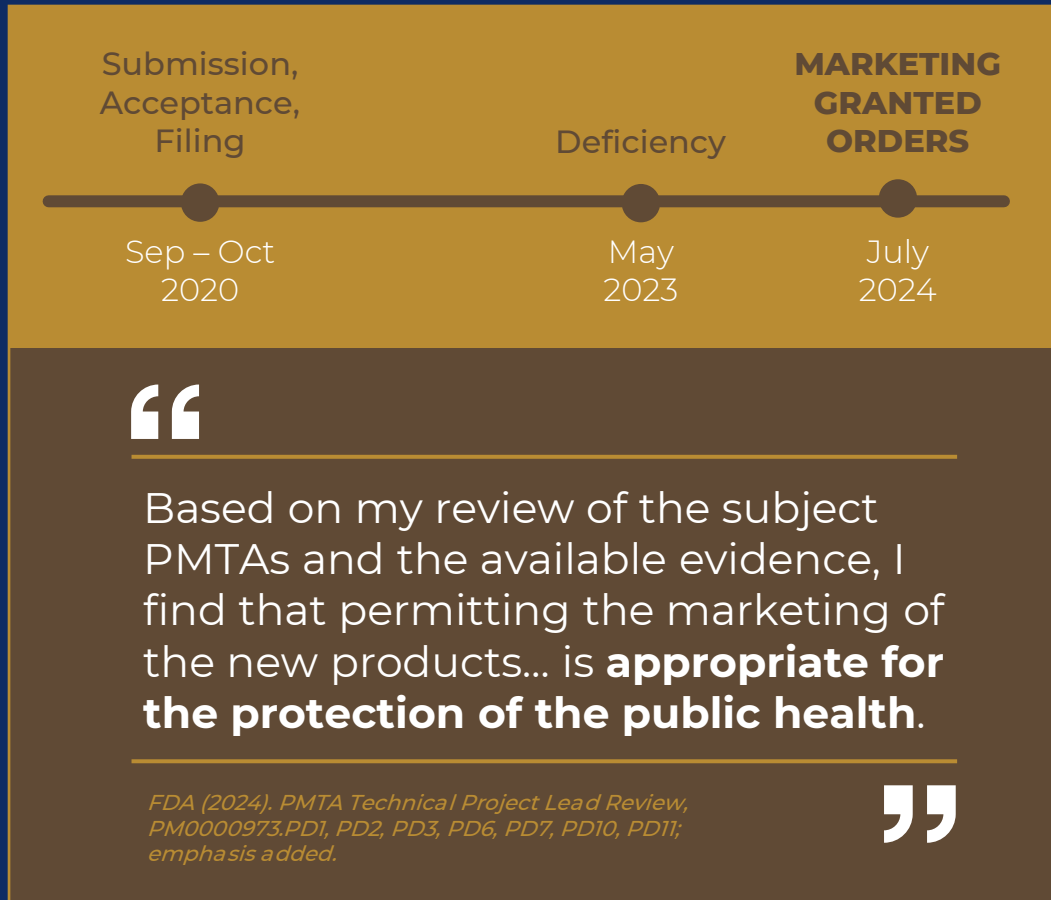
# Agenda



- Vuse Alto and the FDA
- Role of flavors in smoking cessation
- FDA current position on ENDS flavors
- Tool for assessing public health interventions
- Impact of Vuse Alto Menthol and approach to leveraging a consumer database  
REACH / EFFICACY / IMPACT
- Conclusions

# VUSE Alto Marketing Granted Orders

## Received on July 18, 2024



Alto Device

**Golden Tobacco & Rich Tobacco Cartridges**

1.8%, 2.4%, 5.0%

# Vuse Alto Menthol



Alto Device



## Vuse Alto Menthol Cartridge

1.8%, 2.4%, 5.0%

2-pod, 4-pod, 6-pod  
configurations

Alto Menthol Cartridge

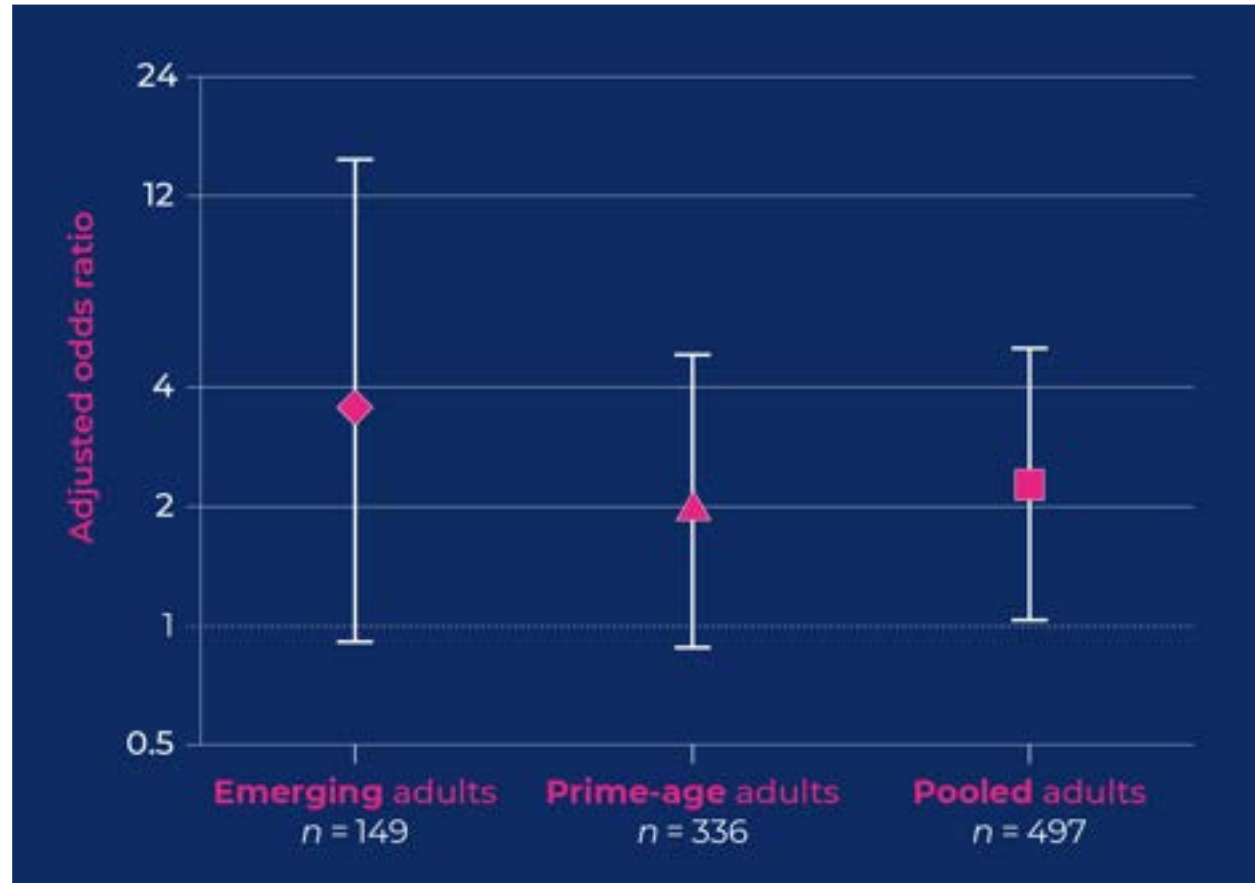
# Role of flavors in smoking cessation

(PATH Waves 1 – 4)

Adjusted Odds Ratio of smoking cessation:  
**Flavored vs. Unflavored**



➔ doi:10.1001/jamanetworkopen.2020.3826



“...among adults who smoked and began vaping, the odds of cessation for those favoring non-tobacco flavors were 2.3 times that of those who used tobacco-flavored e-cigarettes.”

# FDA's stated position on ENDS flavors



APPH evaluation of flavored ENDS, including menthol-flavored ENDS, **“requires evidence that can demonstrate whether [a new flavored ENDS product] will provide an incremental benefit to adult smokers relative to the applicant’s tobacco-flavored product(s).** In particular, the evidence necessary for this evaluation would be provided by either a randomized controlled trial (RCT) or a longitudinal cohort study. The absence of these types of studies is considered a fatal flaw, meaning any application lacking this evidence will likely receive a marketing denial order (MDO)” (2021)



Non-tobacco flavored ENDS need to demonstrate an impact on switching or cigarette reductions compared to tobacco flavored products

# Metric for assessing public health interventions



International Institutes of  
Medicine, Promoting Health:  
Intervention Strategies from  
Social and Behavioral  
Research 2000

**“...in evaluating public health interventions, the level of intervention impact must be judged as a function of the intervention’s efficacy in terms of producing individual change, as well as its reach or penetration within the population”**

# Impact of Vuse Alto Menthol

## REACH

Alto Menthol has a broader reach than Alto Tobacco and a market comparator (Menthol & Tobacco)

## EFFICACY

Alto products demonstrate a robust efficacy in switching smokers

## MAGNITUDE OF IMPACT

The population impact of Alto Menthol far exceeds Alto Tobacco and market comparators

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### Longitudinal Cohort Study

- Cross sectional analysis
- Established smokers (current or former) who use Vuse Alto

### Retrospective Longitudinal Cohort Study

- Retrospective consumer outcomes
- Subpopulation of consumers who reduce cigarettes to 0

## EFFICACY

Alto products demonstrate a robust efficacy in switching smokers

### Longitudinal Tobacco Use and Transitions Survey (LTTS)

- Established smokers currently using Alto
  - 30-day smoking abstinence captured at two-year timepoint

### PATH data Waves 6 & 7

- Switching in smokers who switched to ENDS

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= Conventional



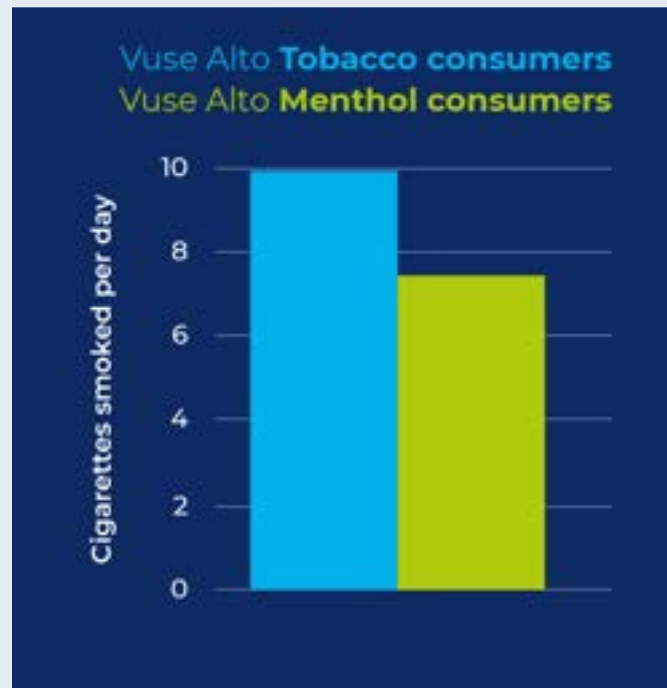
= Unconventional

# REACH: Cross-sectional survey

## Conventional Data Set



**Vuse Alto reach**  
in current and former smokers



**Cigarettes smoked**  
per day in dual users

n = 1,066

Current or  
former smokers  
with >12 months  
Vuse Alto use

Vuse Alto Menthol  
ENDS have greater  
reach and support  
fewer cigarettes per  
day vs Vuse Alto  
Tobacco

# REACH: Retrospective Longitudinal Cohort Study (RLCS)

## *Unconventional Data Set*



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### Consumer database

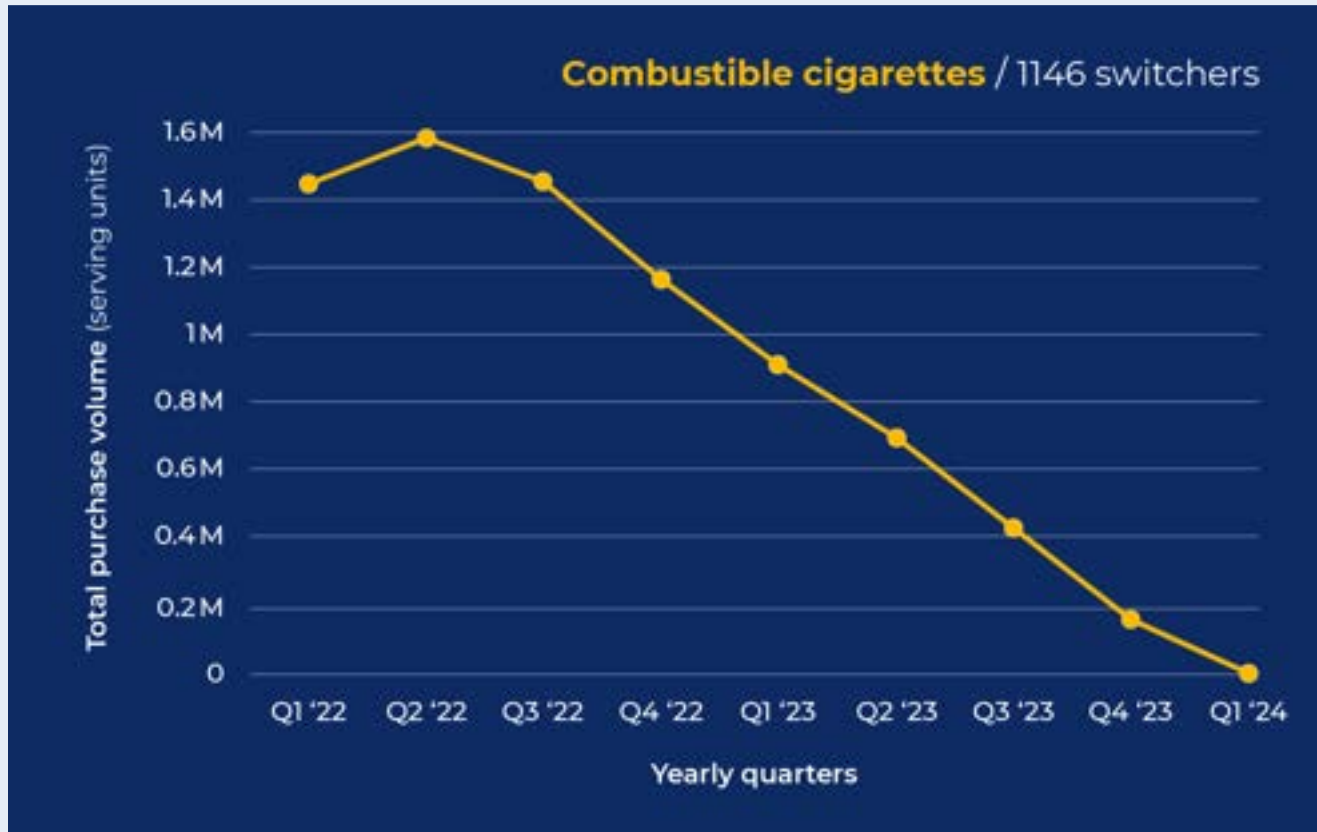
**132 million** data points  
**120 unique** locations  
**49** States

SKU-level retail data

Consumer purchasing-behavior over time

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# REACH: Retrospective Longitudinal Cohort Study

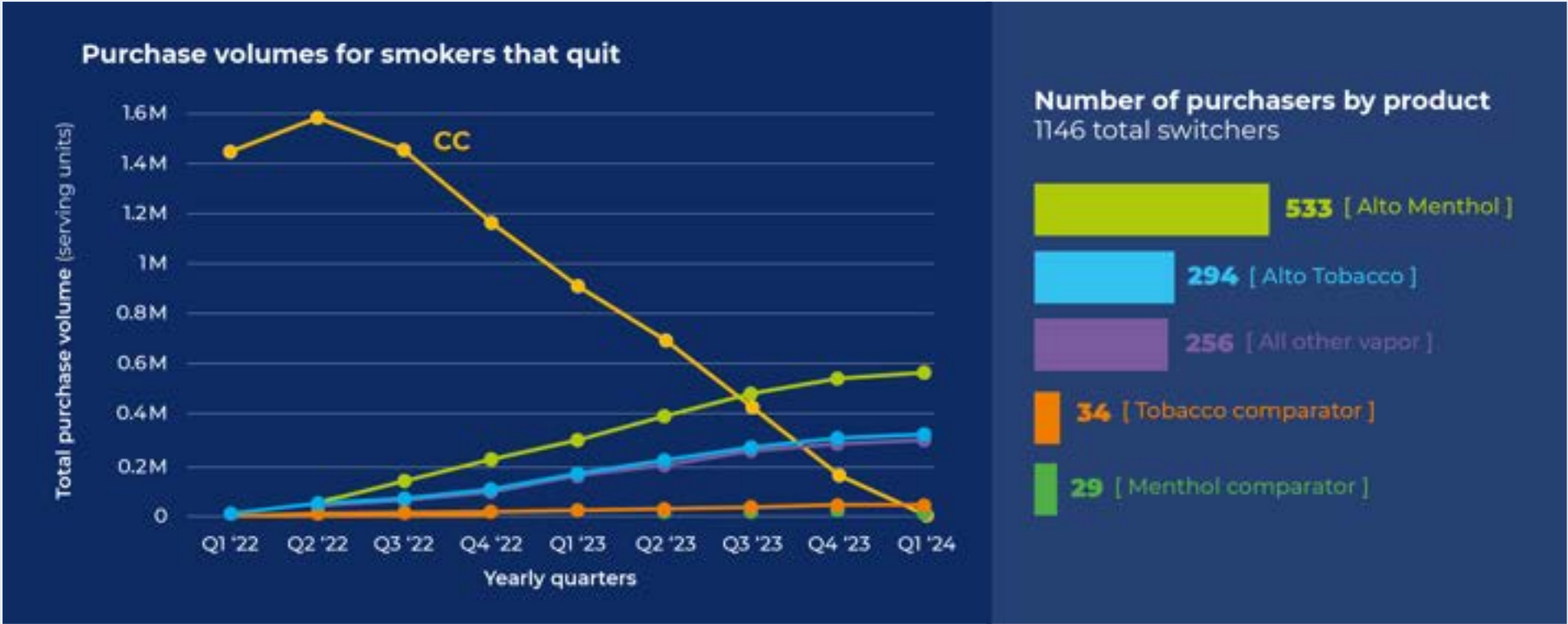


Purchase volumes for smokers that quit

- 24 months of data in the database for the unique purchaser ID
- At first observation in the database, had purchased cigarettes at least once and cigarette purchases were  $\geq 70\%$  of all TNP purchases
- Purchased ENDS during the observation period
- Did not purchase any cigarettes by the end of the observation period

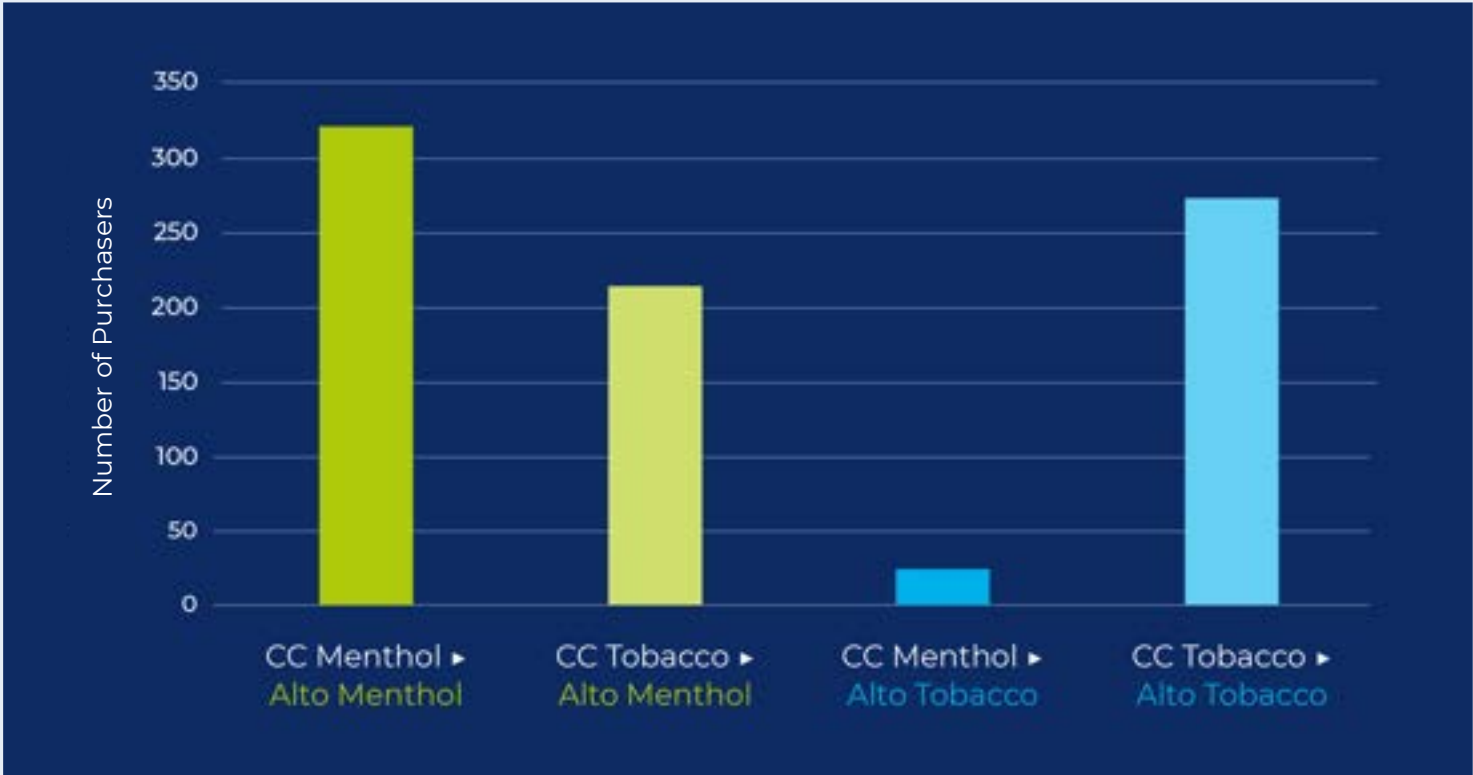
Consumer purchasing data tracks consumers who switch to other tobacco and nicotine products.

# REACH: Retrospective Longitudinal Cohort Study



Substantially more smokers that quit purchasing cigarettes, purchased Vuse Alto Menthol (47%) versus Vuse Alto Tobacco (26%), a market comparator menthol (2.5%), and all other pod-based vapor products (25%).

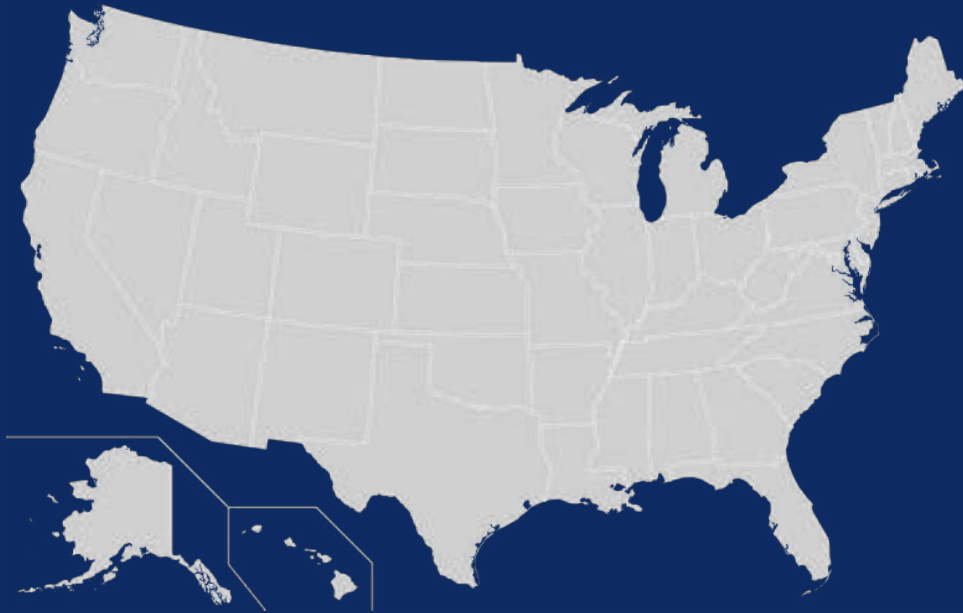
# REACH: Retrospective Longitudinal Cohort Study



Vuse Alto Menthol supports switching for both non-menthol and menthol smokers

Original CC flavor of smokers who switched to ENDS

# Benefits of Using Consumer Database



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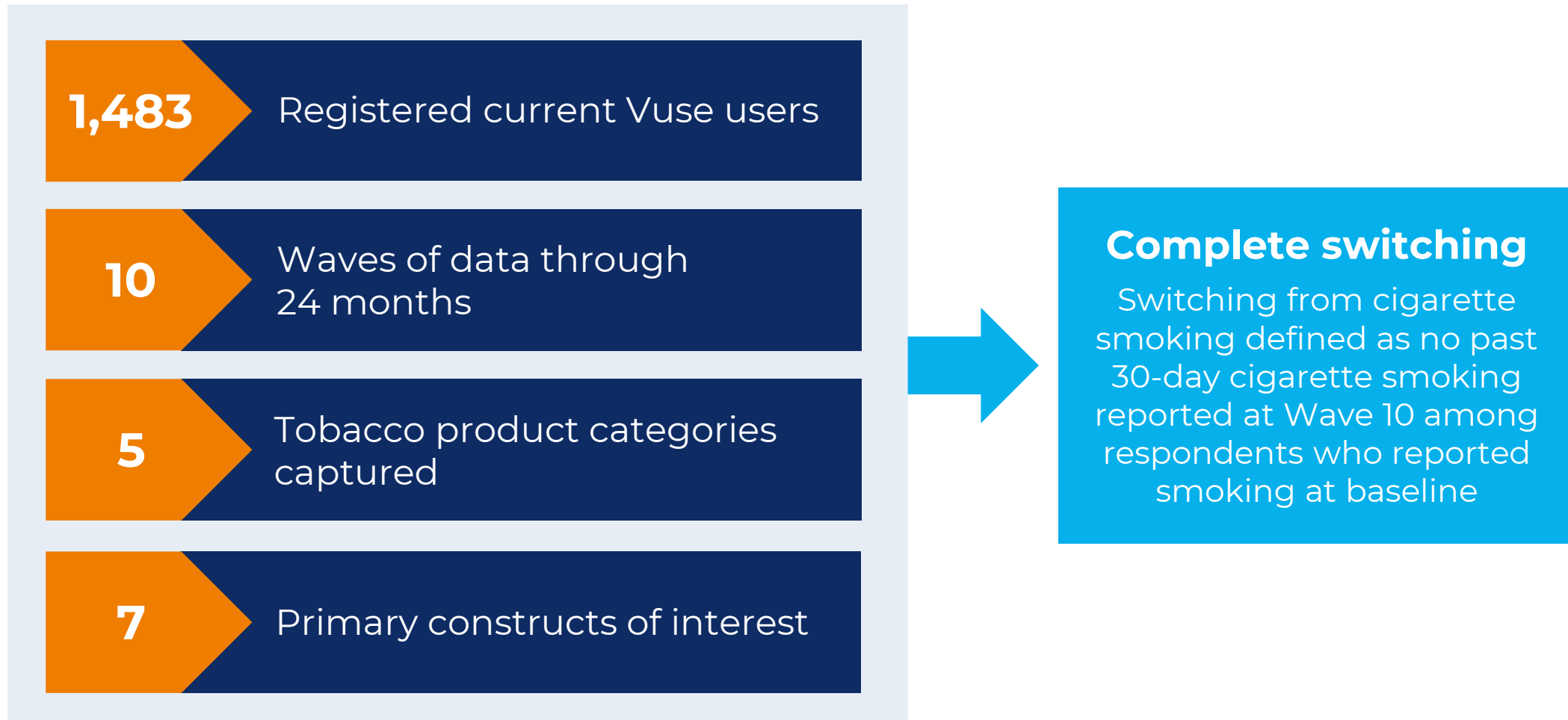
Robust consumer sampling,  
straight from the source

Purchasing data on  
hundreds of products

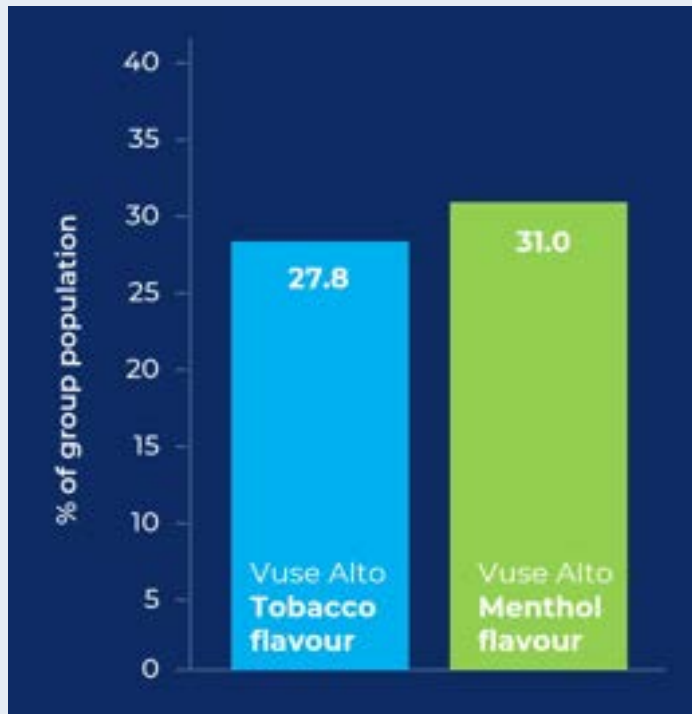
Low manual maintenance

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# **EFFICACY:** Longitudinal Tobacco Use and Transitions Survey (LTTS)



# EFFICACY: complete switching in LTTS over two years



Complete switching at 24 months

## Switching efficacy for Vuse Alto was exceedingly high relative to:

- a market comparator with an MGO (reported at 24.2%)
- Published studies on tobacco-flavored ENDS (8 – 16%)
  - ✓ Carpenter (2023). *eClinical Medicine*  
doi: 10.1016/j.eclinm.2023.102142
  - ✓ Carpenter (2011). *Archive of Internal Medicine*  
doi: 10.1001/archinternmed.2011.492
  - ✓ Carpenter (2004). *Journal of Consulting and Clinical Psychology*  
doi: 10.1037/0022-006X.72.3.371
  - ✓ Hughes (2004). *Addiction*  
doi: 10.1111/j.1360-0443.2004.00540.x

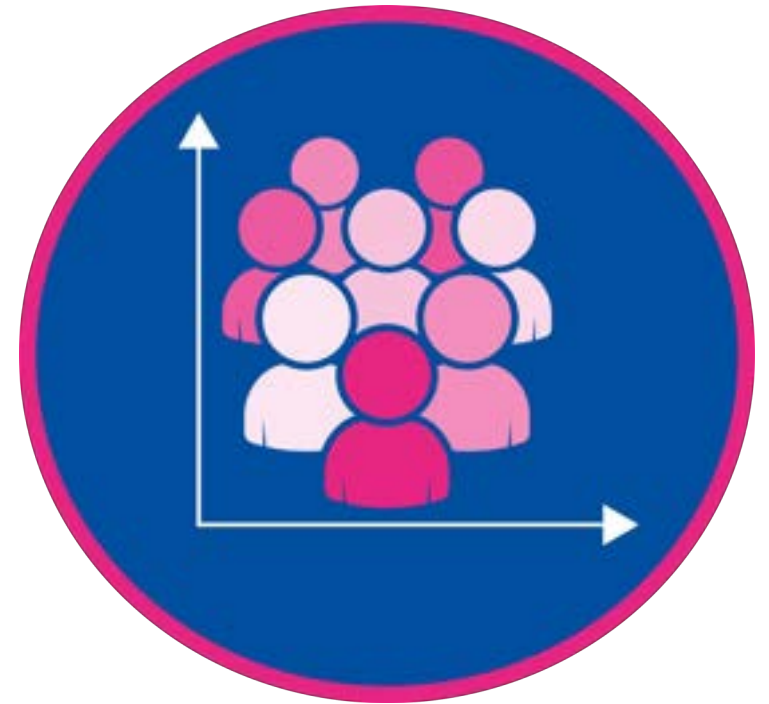
Vuse Alto ENDS support higher complete switching compared to a market comparator



**National survey proctored by the NIH and FDA to evaluate tobacco health and behavior in the U.S.**

## **Analysis**

- Evaluated most frequently reported flavor and preferred brand of ENDS among those who smoked in Wave 6 ( $n = 214$ )
- Analyzed rates of switching in Wave 7 among Vuse Menthol users relative to tobacco-flavored ENDS users.



## Breakdown of analysis cohorts

Switchers were identified if they were flagged as a "former established smoker" and had no past 30-day smoking in Wave 7, while simultaneously reporting electronic nicotine delivery system (ENDS\*) use in Wave 7

| Analytic cohort                         | Definition                                                                                                                          | Sample size |
|-----------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------|-------------|
| <b>Vuse Menthol Users</b>               | Wave 6 cigarette smokers who reported their most often used ENDS brand is Vuse and most often used ENDS flavor is menthol at Wave 7 | 47          |
| <b>All Menthol Pod-Based ENDS Users</b> | Wave 6 cigarette smokers who reported their most often used ENDS flavor is menthol at Wave 7 regardless of brand (Vuse included)    | 109         |
| <b>All Tobacco Pod-Based ENDS Users</b> | Wave 6 cigarette smokers who reported their most often used ENDS flavor is tobacco at Wave 7 regardless of brand (Vuse included)    | 58          |

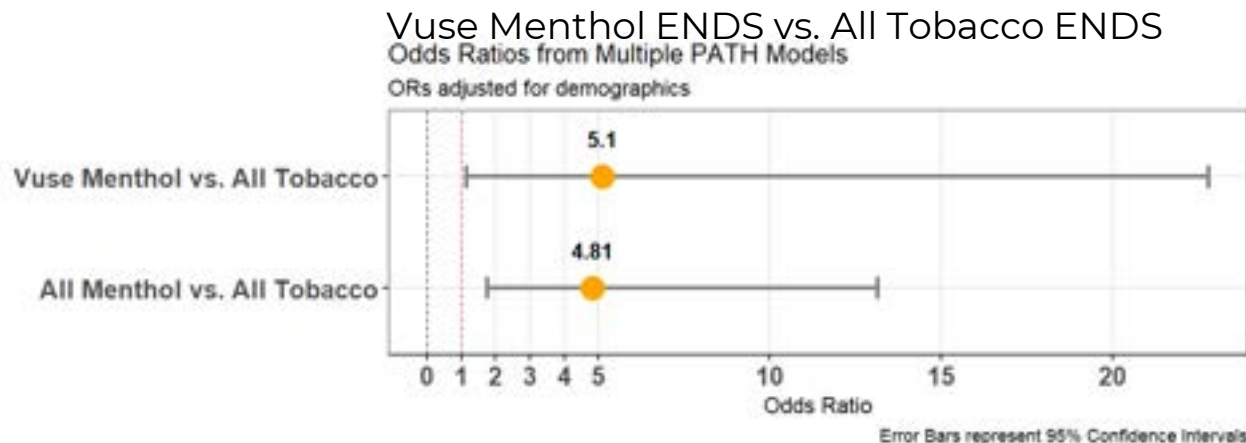
\*Vuse products assumed to be Alto based on sales data of the same PATH period.

# EFFICACY: PATH

**Research Question: What were the odds of switching for Vuse Menthol Users relative to Tobacco pod-based ENDS users?**



Evaluated preferred ENDS in smokers who switched from cigarettes to ENDS between Waves 6 and 7



Smokers who used Vuse Menthol pod ENDS had higher odds (**5.10 times**) of switching compared to Tobacco pod ENDS

Smokers who used Menthol pod ENDS had higher odds (**4.81 times**) of switching compared to Tobacco pod ENDS

# Conclusions: IMPACT

- ✓ Utilization of a consumer purchasing database provided insights into behavior and impact of Vuse Alto Menthol in switching smokers
- ✓ Vuse Alto Menthol, and menthol-flavored ENDS generally, have greater reach than tobacco-flavored ENDS
- ✓ Vuse Alto Menthol users smoke fewer cigarettes per day compared to Vuse Alto Tobacco
- ✓ Vuse Alto Menthol, and menthol-flavored ENDS generally, are more effective than tobacco-flavored ENDS at helping smokers switch completely away from cigarettes



Multiple lines of evidence demonstrate the benefit of Alto Menthol vs Tobacco ENDS and market comparators in switching smokers.

# QUESTIONS



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