



Consumer Driven Real-World Data: The Vuse Alto Story

15th April 2025

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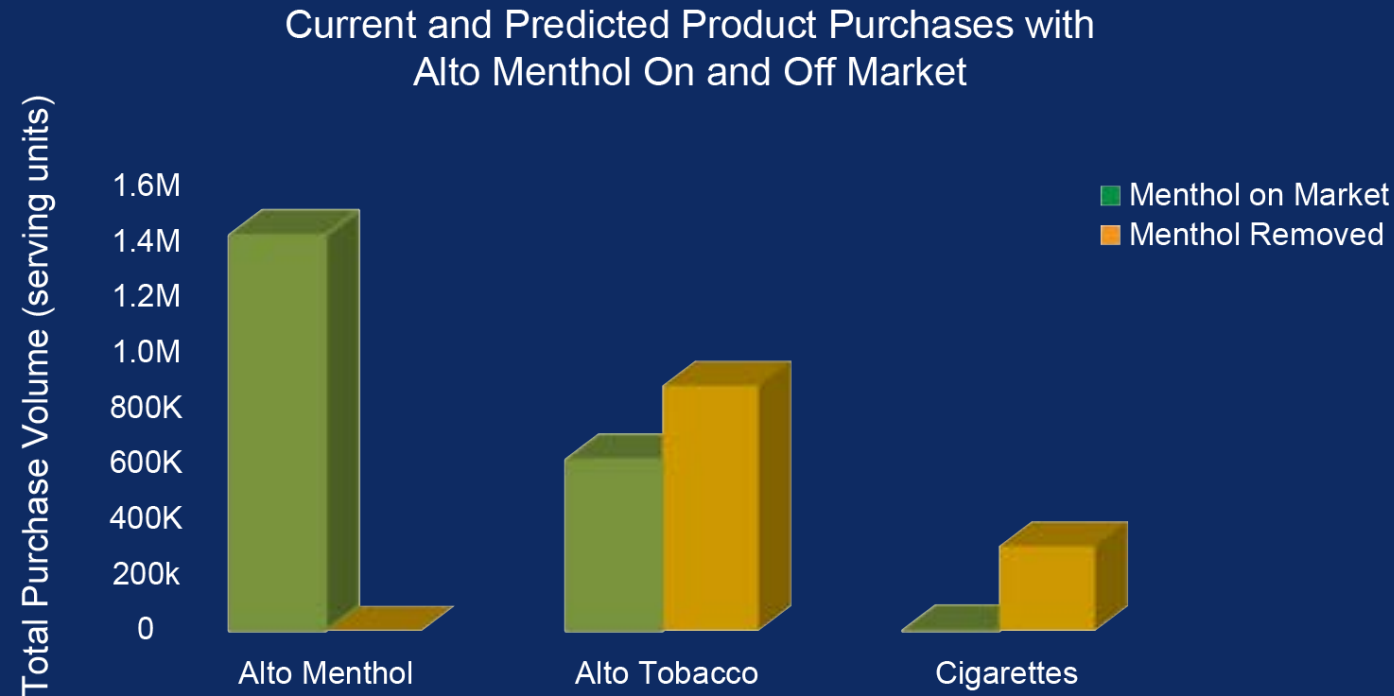
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Overview

- 1 Defining RWD in the context of Consumer Products
- 2 Data, Populations, and Defining Impact
- 3 Retrospective Longitudinal Cohort Study: Alto Menthol
- 4 Summary and Considerations

Unintended Consequences of Removing Alto Menthol



Survey data suggest, of current Alto Menthol users, 43.4% will switch to Alto Tobacco and 56.6% will return to cigarettes if Alto Menthol is removed (56.6%; (51.5, 61.6); n = 279)

Removal of Vuse Alto Menthol from the market will be a detriment to public health if consumers switch back to smoking combustible cigarettes.



Real-World Data for Consumer Products

Definitions

Real-world Data: Patient health status and routine care obtained from medical records, claims or registries.

Real-world Evidence: Clinical evidence about usage and potential benefits and risks of medical products.

Interventional: A clinical trial in which volunteers are assigned to one or more interventions to assess effects of health outcomes

Non-interventional: Observational studies in which patients receive a marketed drug during routine care.

Can the intent of current guidance for RWD be applied to consumer facing tobacco products through the utilization of Consumer Databases?

Considerations for the Use of Real-World Data and Real-World Evidence to Support Regulatory Decision-Making for Drug and Biological Products. FDA, 2023

The Question

Can the intent of current guidance for RWD be applied to consumer facing tobacco products through the utilization of Consumer Databases?

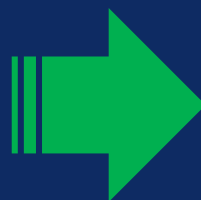
The Definition

Data that capture consumer purchasing, product usage, and/or behavioral changes that would be indicative of changes to individual or population health risks and benefits.

The Data

These data can directly, or with the support of additional data, provide an assessment of product category transitions and behavioral changes over time. **Understanding consumer/product interactions helps define the potential impacts of reduced risk products.**

Assessing Consumer Populations



Scope of the Data

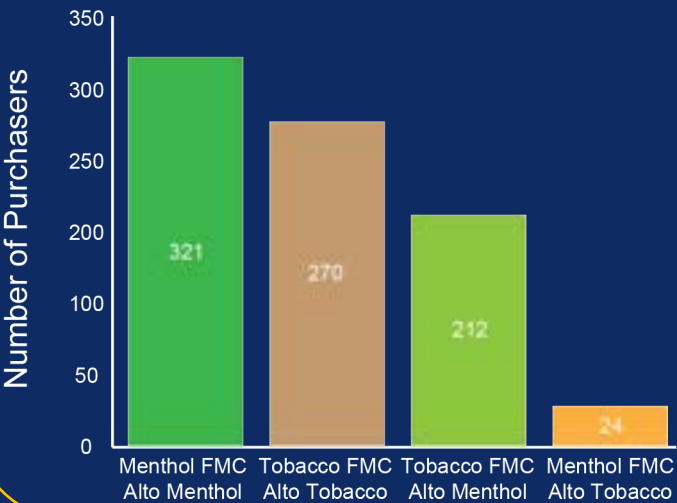
- Purchasing Volumes
- Product Category Insights
- Switching (complete transitions in purchasing)
- Dual Use (partial transitions in purchasing)
- Regional Differences in Product Use
- State-by-State Comparisons

RWD from Consumer Databases allows for the evaluation of product adoption and behavioral changes over time with implications for **post-market surveillance and the assessment of population-level risk reductions of the consumer population.**

Population Impact of Products

Product Selection

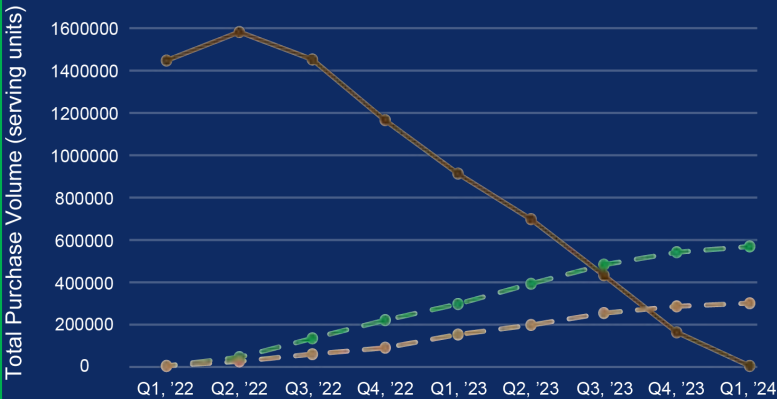
Number of Switchers by UB and Flavor



Product selection, by previous product used, provides valuable insights about transitions and migration.

Smoking Transitions

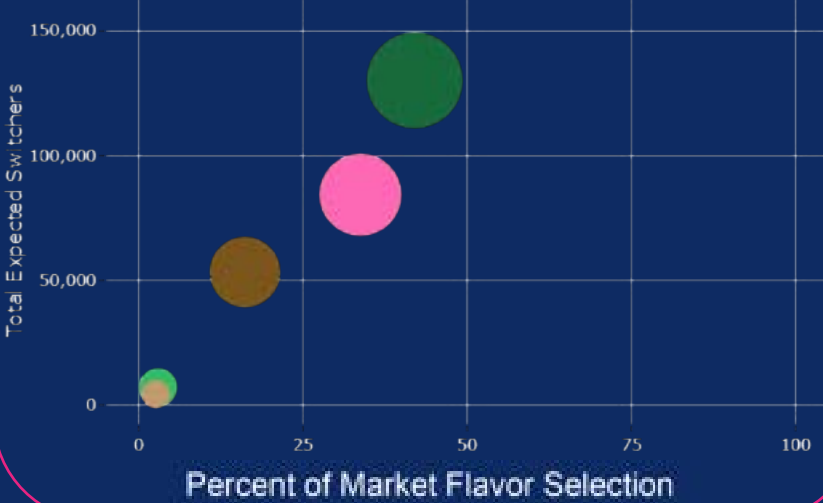
Purchase Volumes for Smokers that Quit



Defining and assessing specific populations provides insights into a product's population-level benefit.

Population Impact

Expected Population Switching



Understanding the scope of product use behaviors allows for a mapping of product impact on the population.

Retrospective Longitudinal Cohort Study (RLCS)



132 million data points
120 unique locations
49 States

Consumer Database

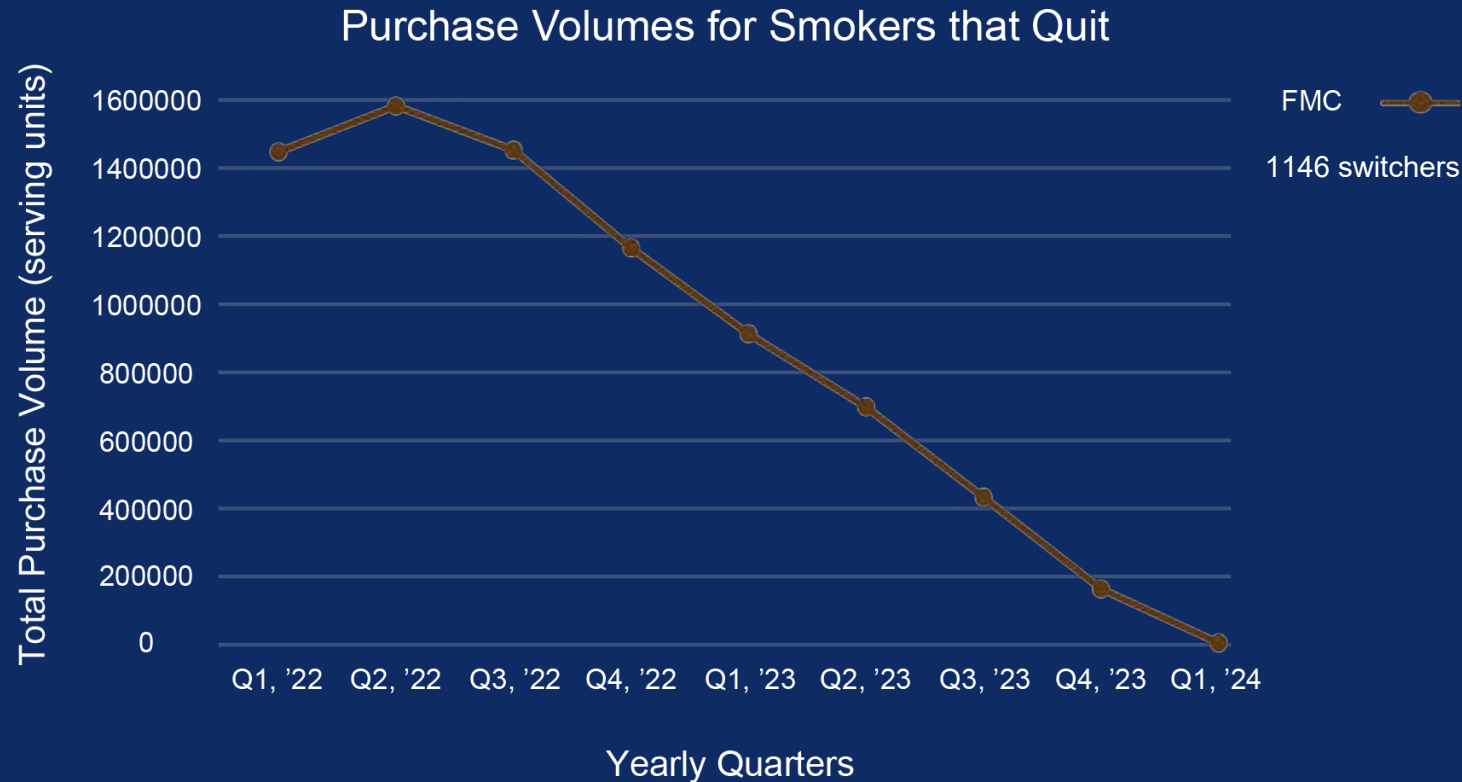
Methods and Sample Size

- ≥ 7 weeks of TNP purchasing data across the 2yr assessment period.
- Purchase ≤ 2 product categories per visit, on average.
- Purchase ≤ 2 packs of cigarettes per day on average
- Purchase ≤ 6 unique TNP brands per quarter.
- Purchase ≥ 2 packs of cigarettes or 2 ENDS cartridges per quarter

A “serving unit” is defined as one cigarette and for these analyzes, one ENDS pod is 20 serving units.

***Database does not include illicit products**

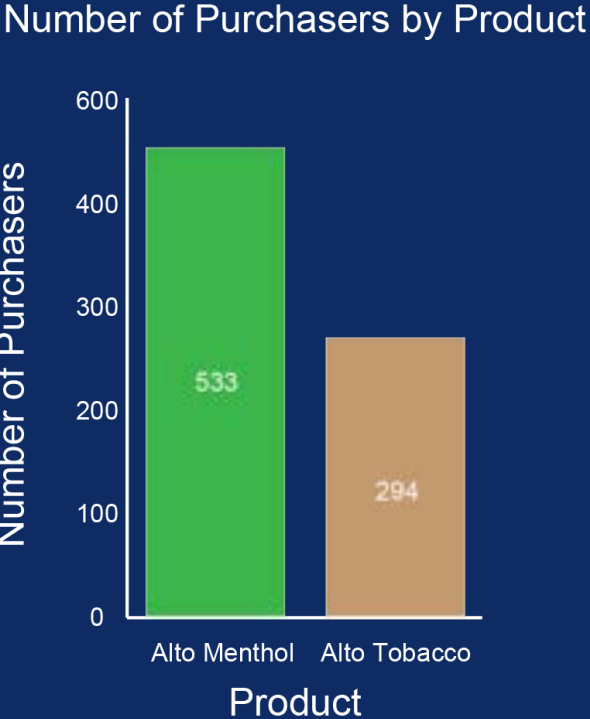
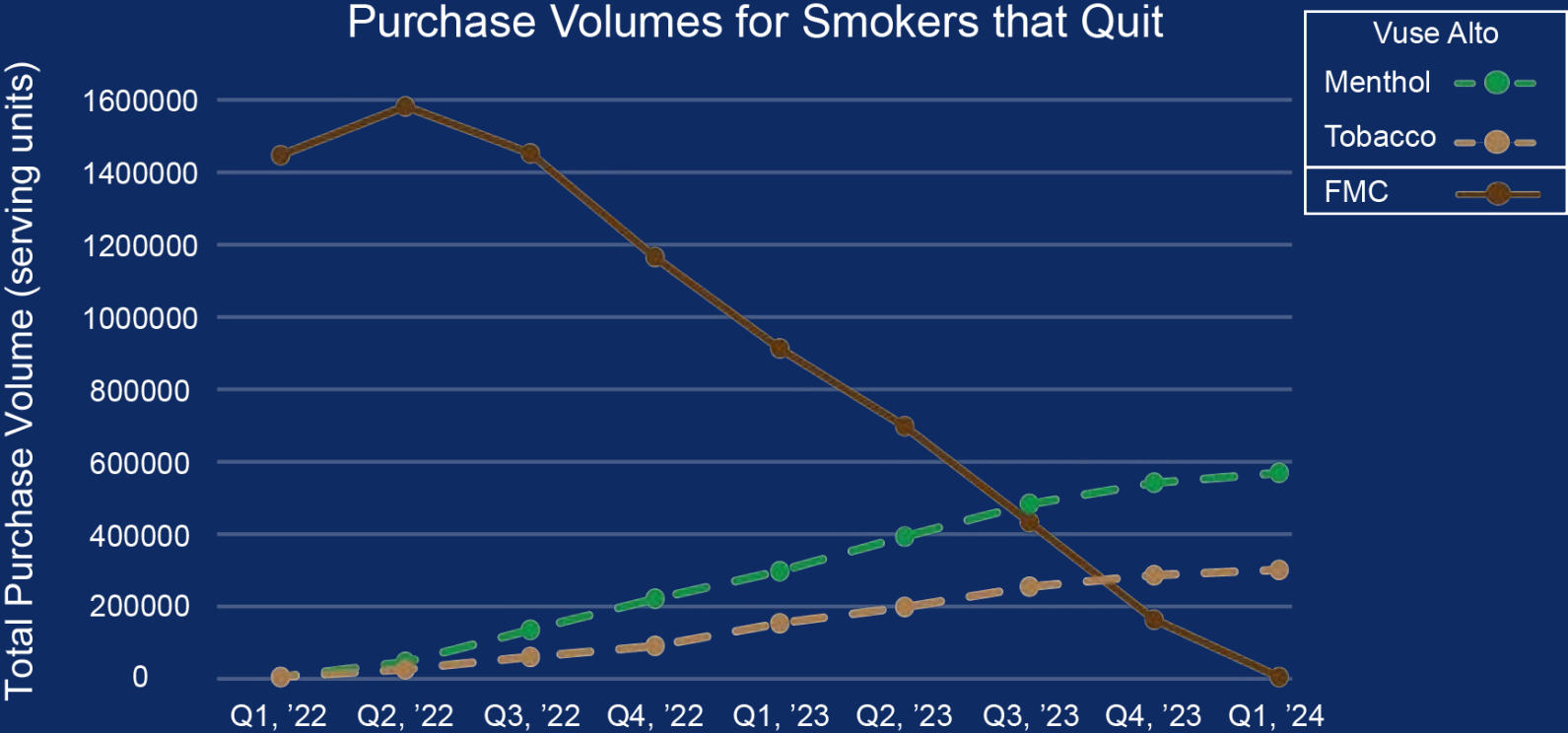
Retrospective Longitudinal Cohort Study



- 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 allows for the tracking of consumer who switch to other tobacco and nicotine products.

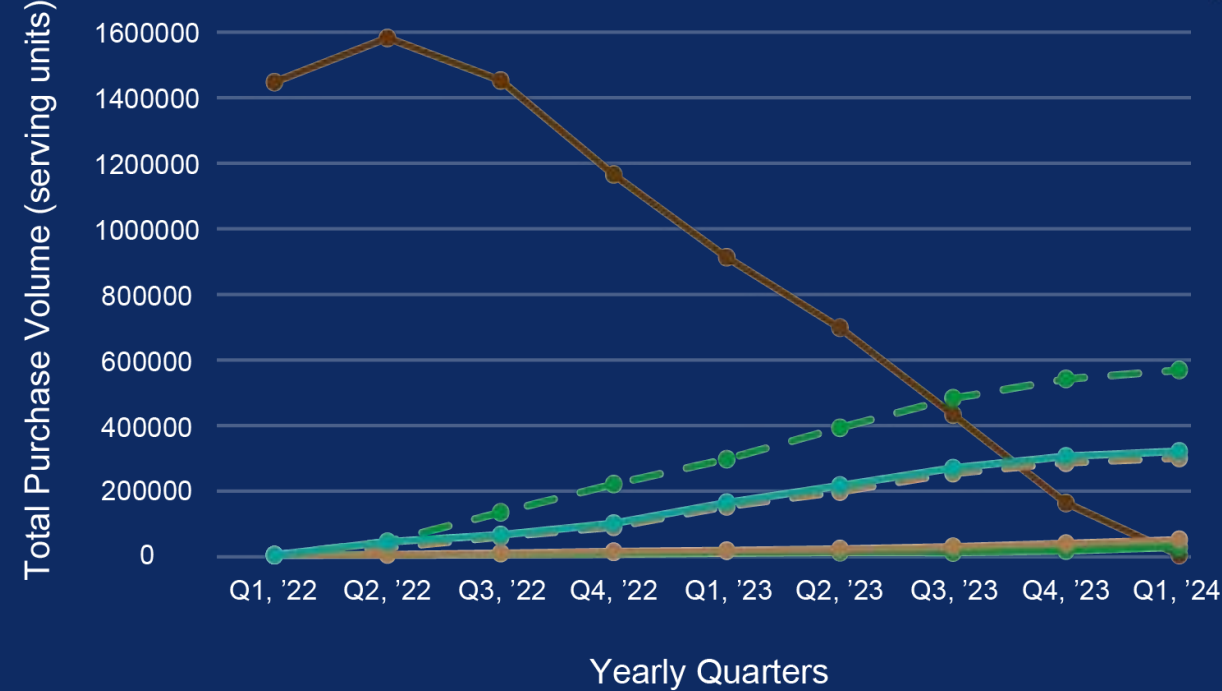
Retrospective Longitudinal Cohort Study



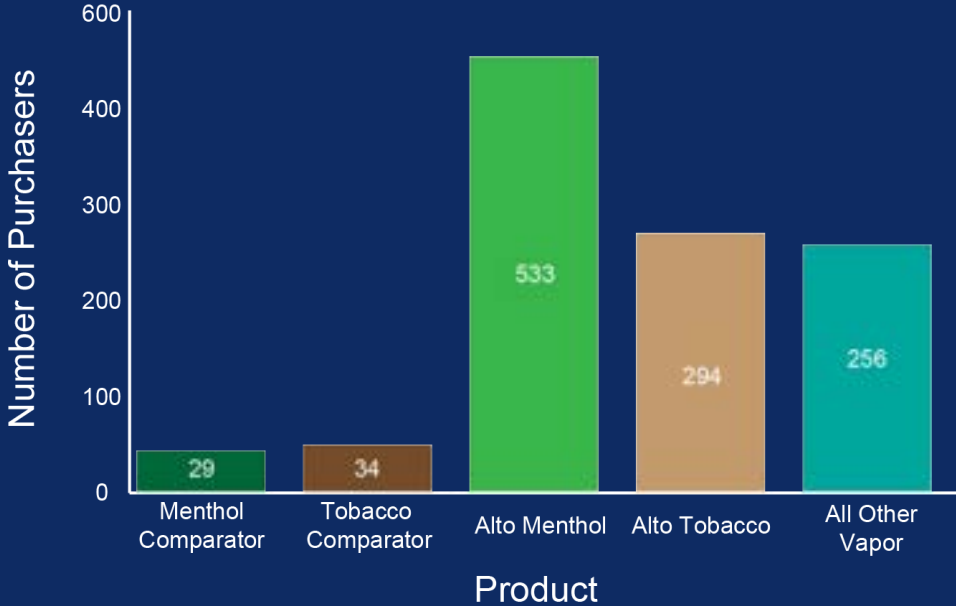
Alto Menthol purchases accounted for 42% more of the purchase volume compared to Alto Tobacco for those that quit purchasing cigarettes.

Retrospective Longitudinal Cohort Study

Purchase Volumes for Smokers that Quit



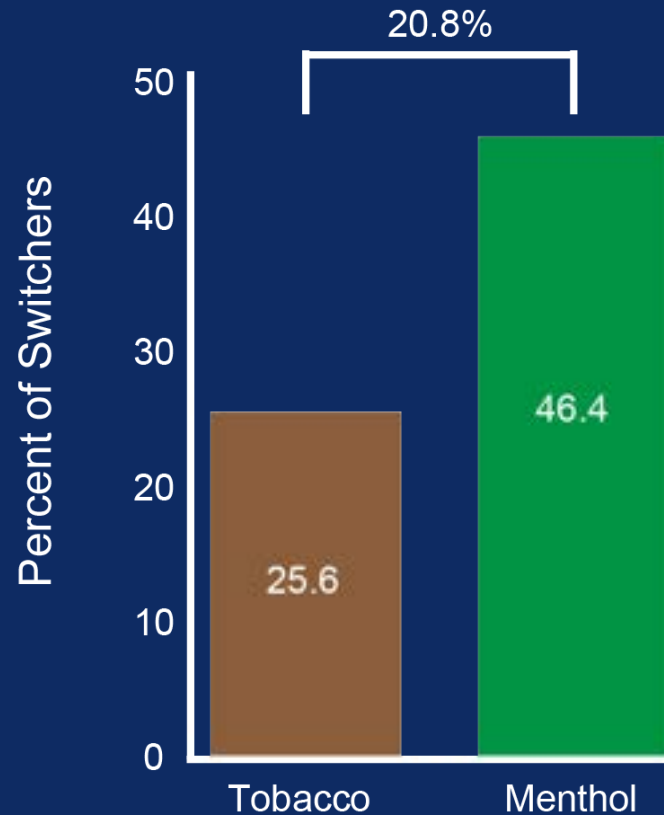
Number of Purchasers by Product



Substantially more smokers that quit, purchase Alto Menthol (46%) versus a Market Comparator Menthol (2.5%) and all other pod-based vapor products (25%).

RLCS Switchers: Menthol vs Tobacco

Flavor Selection for Switcher Population



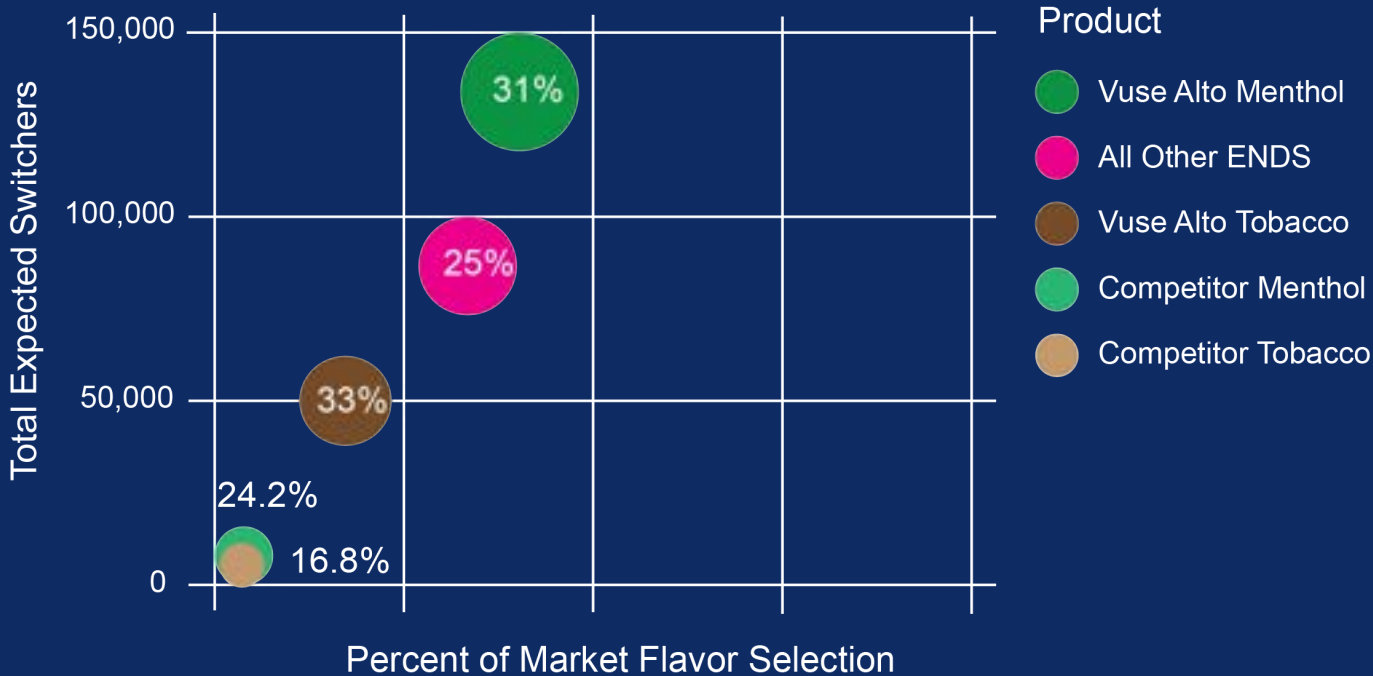
Importance of Menthol

46% of the population of vapor purchasers who switched from cigarettes purchased Alto Menthol vs Alto Tobacco (25.6%), Market Comparator Tobacco (3.0%), and Market Comparator Menthol (2.5%).

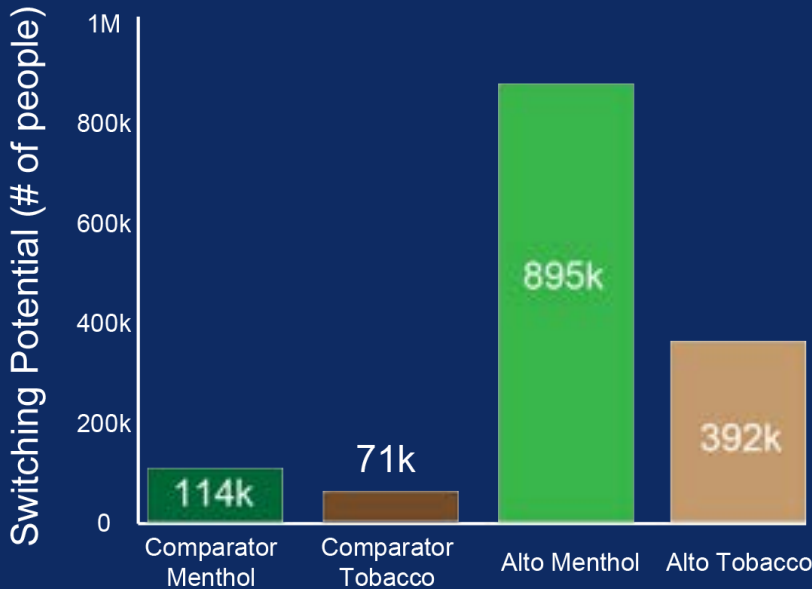
Alto Menthol was purchased at far greater rates than Alto Tobacco by those switching away from cigarettes

Alto Menthol Likely to Have the Greatest Population Impact

Expected Switching Among a Hypothetical Population
(1,000,000 smokers)



Population Impact: Estimated from Current Smoker Population



Alto Menthol likely to have the greatest population impact

- Switching (data from TPL reports and published literature) and Flavor Selection (% of population) provide the projected population impact

Population estimate based on CDCs estimated 28.8M cigarettes smokers. (Population x percent vapors that were former smokers) x (Percent of switcher pop by flavor) x (switching).

Alto Menthol: Consequences and Benefits

Alto Menthol accounts for 46% of products purchased by those that switched away from combustible cigarettes

Purchasing data, in conjunction with data for consumer intentions, reflects an overly negative impact to the population if Alto Menthol is removed from the market.

These types of data have been largely dismissed by regulatory agencies, but provide insight into consumer behaviors beyond what is achievable in controlled studies.