

# ENDS Flavors:

Their Role in Initial Liking at Trial,  
Preference Formation, and Switching

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June 6<sup>th</sup>, 2018  
ENDS Conference



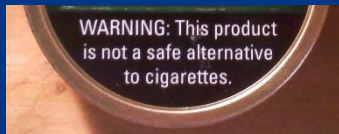
# Altria's Corporate Structure



*\* For illustrative purposes only. Does not reflect all Altria subsidiaries.*

# Tobacco Harm Reduction at Altria

**Communicating  
about the health  
effects of  
tobacco use**



**Help Reduce  
Underage  
Tobacco Use**



**Supporting  
Cessation**



**Developing &  
Marketing  
Lower-Risk  
Tobacco  
Products**



**We aspire to be the U.S. leader in authorized, non-combustible,  
reduced-risk products**

# FDA Recognizes Continuum of Risk

*"We must recognize the potential for innovation to lead to less harmful products, which, under FDA's oversight, could be part of a solution. While there's still much research to be done on these products and the risks that they may pose, they may also present benefits that we must consider."*

Dr. Scott Gottlieb  
FDA Commissioner

## Continuum of Risk

**Combusted Tobacco Products**

**Non-combusted Tobacco Products**

**MOST  
HARMFUL**

**LEAST  
HARMFUL**

July 28, 2017: Protecting American Families: Comprehensive Approach to Nicotine and Tobacco  
<https://www.fda.gov/NewsEvents/Speeches/ucm569024.htm>

# Product Platforms

## E-Vapor/ENDS



## Oral Tobacco/ Nicotine Products



## Heated Tobacco Products



# Diverse MarkTen® Flavor Portfolio



# Regulatory Environment

**Federal Register / Vol. 83, No. 55 / Wednesday, March 21, 2018 / Proposed Rules**

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DEPARTMENT OF HEALTH AND  
HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 1100, 1140, and 1143

[Docket No. FDA-2017-N-6565]

RIN 0910-AH60

Regulation of Flavors in Tobacco  
Products

**AGENCY:** Food and Drug Administration,  
HHS.

**ACTION:** Advance notice of proposed  
rulemaking.

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## *D. The Potential Role of Flavors in Facilitating Transition From Cigarettes to Tobacco Products That May Pose Less Risk*

5. Provide studies or information regarding the role of flavors (other than tobacco) in helping adult cigarette smokers reduce cigarette use and/or switch to potentially less harmful tobacco products.

# MarkTen<sup>®</sup> Actual Use Study\*

## Research Question:

What role, if any, do flavor options play in switching behavior associated with MarkTen<sup>®</sup>?

- ❑ We conducted an 8-week, 2-phase, actual use study with 614 adult cigarette smokers not planning to quit
- ❑ We characterized MarkTen<sup>®</sup> (M10) e-vapor use behavior and its influence on other tobacco use behavior
- ❑ We examined the potential role of flavor variety (14 flavors) on behavioral outcomes

\*Some info presented elsewhere: Vansickel AR, Cheng H, Largo E (2018). The role of MarkTen<sup>®</sup> e-vapor flavor variety in cigarette smoking reduction among adult cigarette smokers not planning to quit smoking: results of a 6-week at-home use study. Poster presented at the Society for Research on Nicotine and Tobacco meeting in Baltimore, MD.



## Key Findings

1. All 14 flavors:
  - were needed to meet participant preferences<sup>a</sup> at trial and
  - were used<sup>b</sup> during the 6-week phase
2. Flavor preferences changed and participants' consideration sets narrowed over time
3. Participants that switched generally used more flavor varieties
4. Greater flavor usage = greater reduction in cigarettes after 6 weeks

a: based on highest rating of liking (initial liking at trial)

b: used by at least one participant on at least 1-day each week

# Actual Use Study: Sample Disposition

Screening N = 2,065



**614  
Smokers**

**Adult Cigarette Smokers = 344**

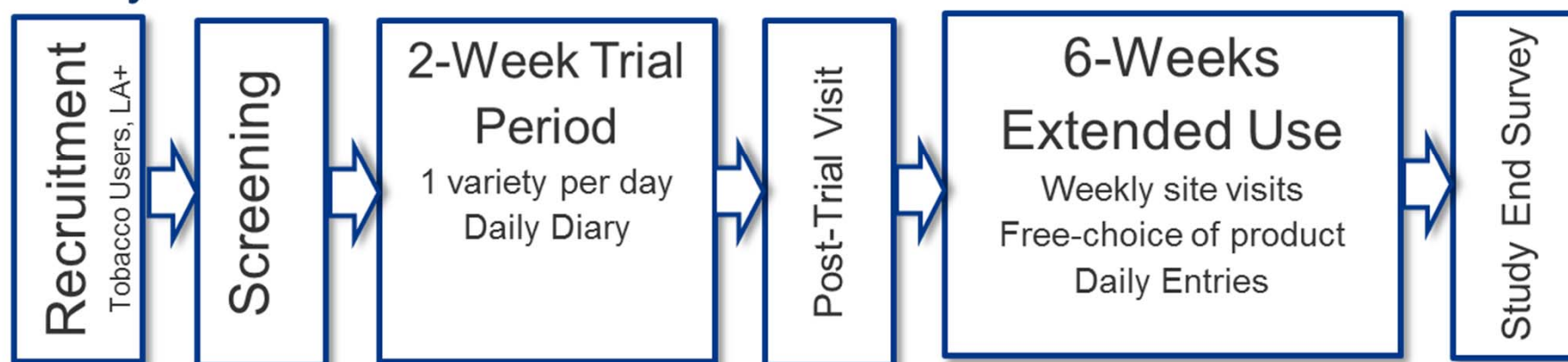
**Adult Dual E-Vapor/Cigarette Users = 270**

Exclusive E-Vapor Users = 107 (not reported here)

Lost to follow up: Did not return, even after re-contact  
Product-related: Did not use during trial or did not score  $\geq 3$  on intentions to use  
Noncompliant: Missed 5 or more daily surveys in a row or missed > 2 Day 7 surveys

# Actual Use Study: Overview

## Study Overview



- $\geq 3$  Intentions to Try
- No plans to quit smoking in next 3 months

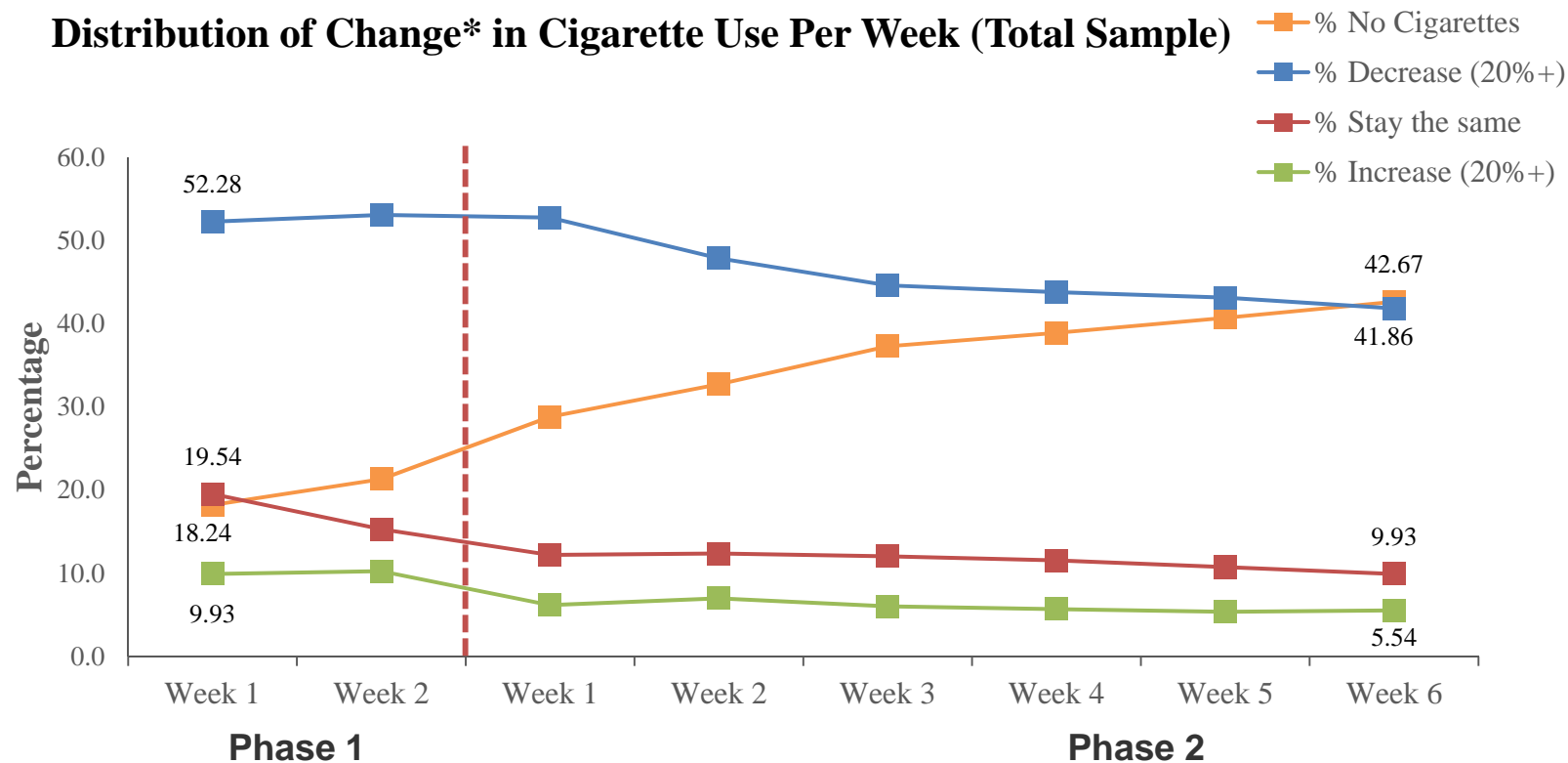
$\geq 3$  Intentions to Use

# Actual Use Study: Strengths and Limitations

- Strengths:
  - Near Real World Conditions (inclusion of individuals that would be likely to try and use product in market, open-access to flavor portfolio, at-home use, self-determined usage levels)
  - Daily data capture of all tobacco use
  - Robust sample
- Limitations:
  - Non-probability based sample
  - Free product
  - Exclusion of smokers planning to quit
  - Study duration

# Participants Reduced Cigarette Smoking Behavior

Distribution of Change\* in Cigarette Use Per Week (Total Sample)

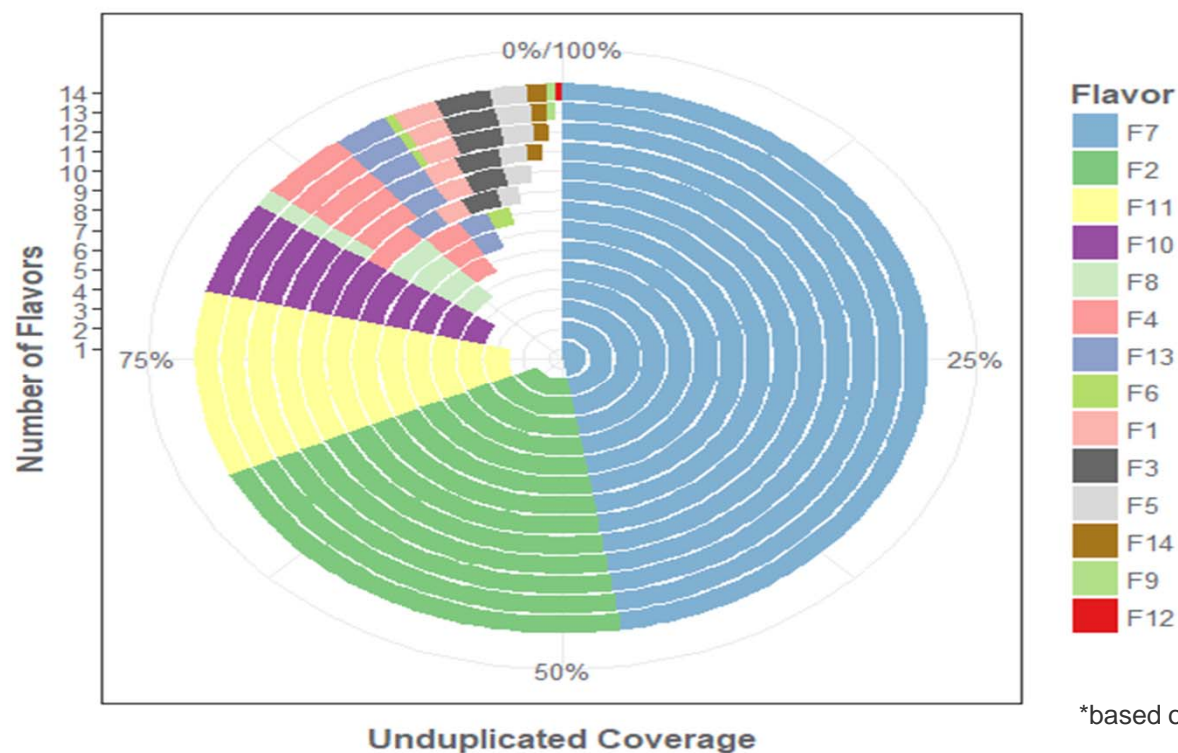


\*Change based on number of cigarettes smoked past 7 days at screening

# 14 Flavors Were Needed to Meet Preferences\* During Trial

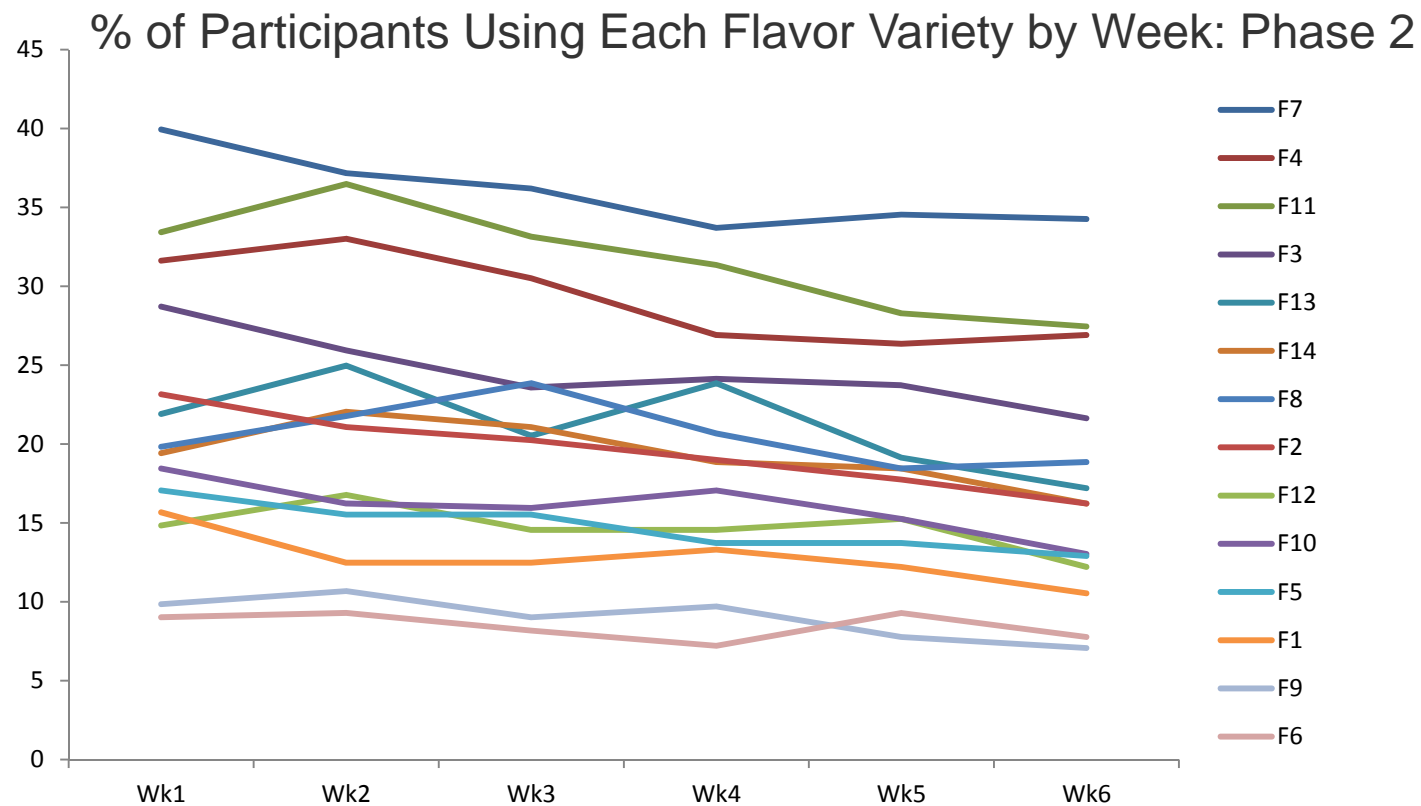
## Total Unduplicated Reach and Frequency Analysis (TURF)

Top Liking Rating (7-point) during Phase 1

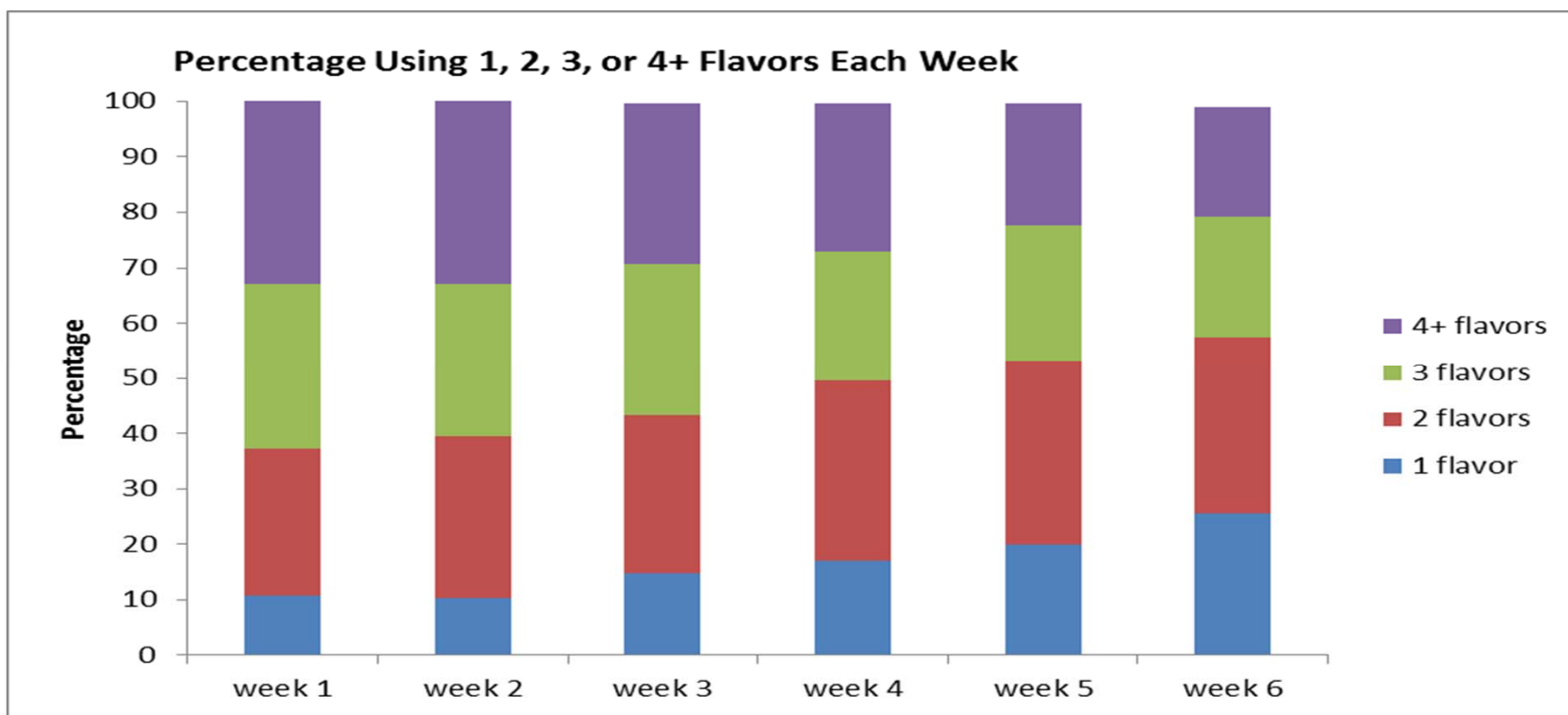


\*based on highest rating of liking

# 14 Flavors Were Used During Phase 2



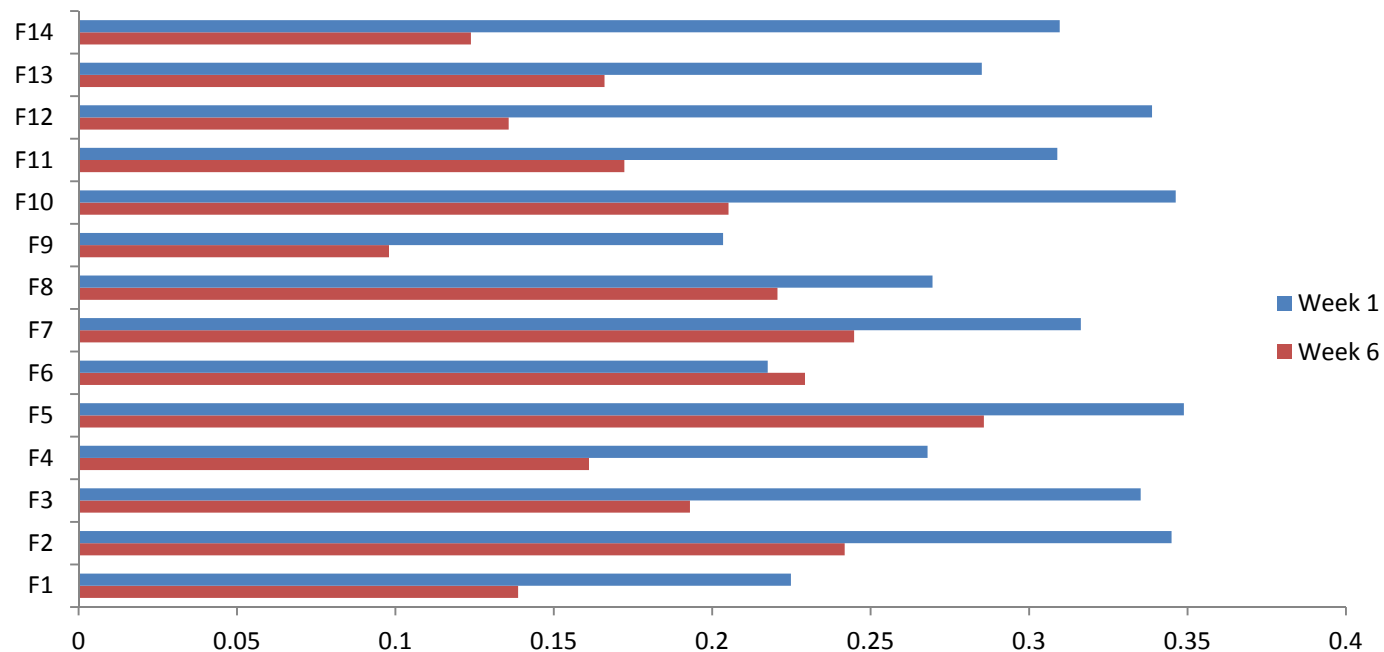
# Flavor Consideration Sets Narrowed Over Time





# Relationships Between Initial Liking and Use Occasions Weakened Over Time

Correlation Coefficients for Relative Liking<sup>a</sup> and Relative Use Occasion<sup>b</sup>



a: Liking scores during trial adjusted for individual ratings overall

b: Use occasions during week 6 adjusted for individual usage levels

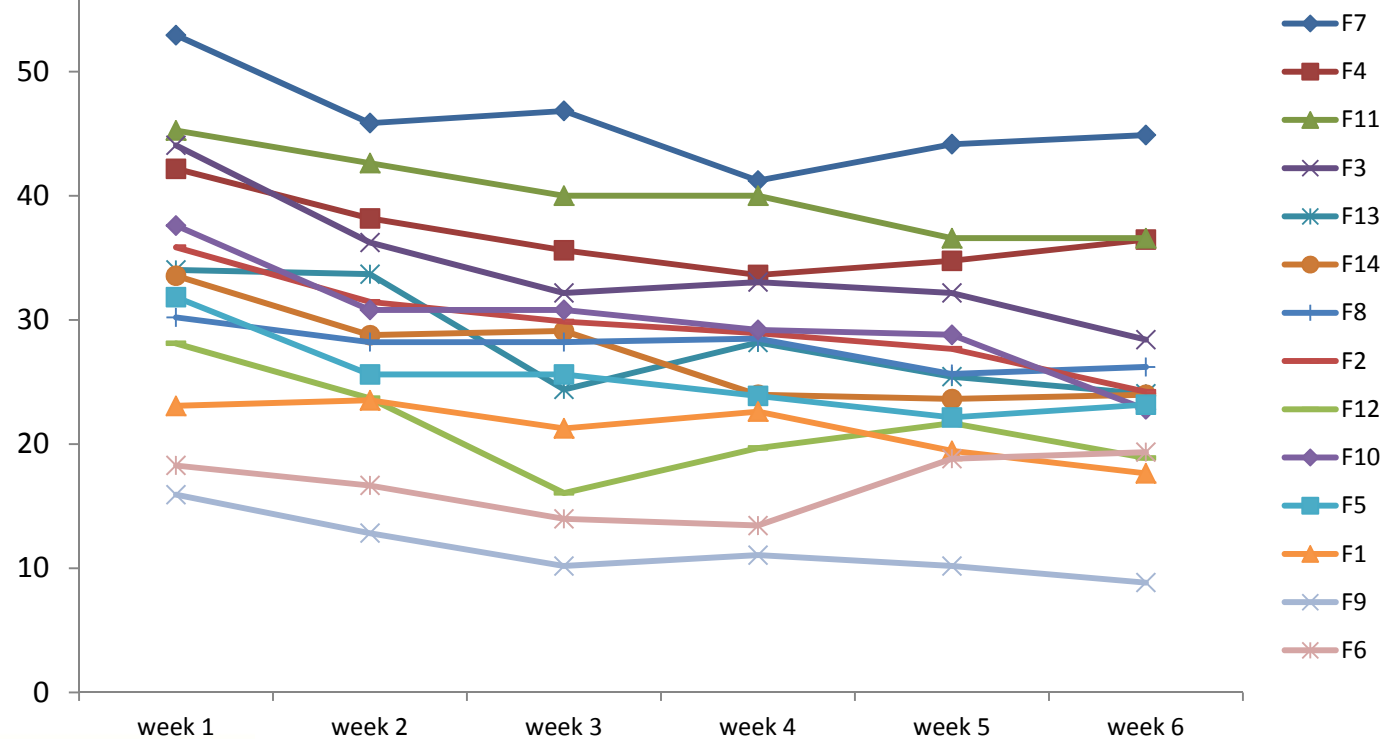


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# Flavor Preferences Changed Over Time

% Participants Used a Flavor Ranked in Their Top 4 Liking during Trial



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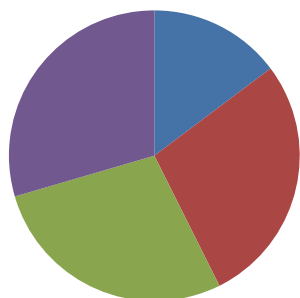
Top 4: The four flavors rated highest on the 7-point liking scale during trial (Phase 1)

# Participants that Switched Used More Flavors

## Number of Flavors Used by Behavioral Outcome

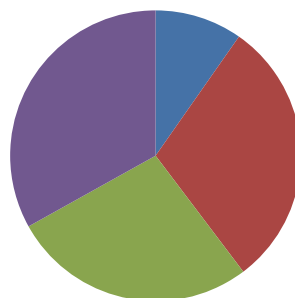
**Smoked Same Amount**

N = 61



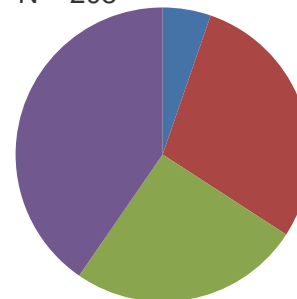
**Decreased<sup>a</sup> Cigarettes**

N = 257



**Switched<sup>b</sup> to MarkTen<sup>®</sup>**

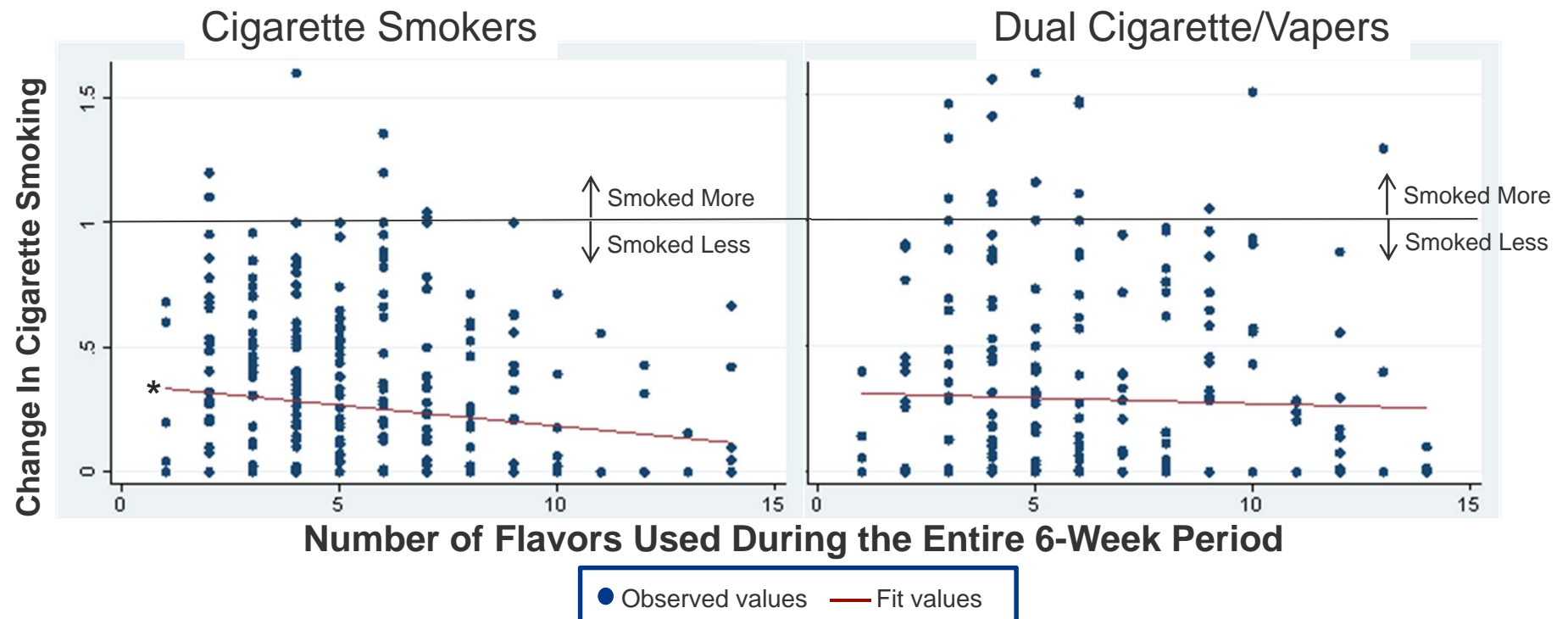
N = 208



■ 1 to 2 varieties  
■ 3 to 4  
■ 5 to 6  
■ 7 or more

	Same	Decrease	Switched
Mean Number of Flavors	5.48	5.92	6.42
S.E.M	0.70	0.37	0.44

# Number of Flavors Played a Role in Smoking Reduction



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\*Significant association between #flavors and week 6 #cigs/baseline  
N = 6 extreme outliers removed from Dual Cigarette/Vapers

## Overall Conclusions

- MarkTen<sup>®</sup> products present an opportunity to reduce the harm from cigarette smoking
- Flavor options play a role in adult cigarette smokers' early trial and adoption of MarkTen<sup>®</sup>
  - A wide variety of flavor options is necessary to capture all adult smokers' preferences
- Flavor usage changes over time and later flavor preferences do not necessarily reflect early liking/preference for flavor options
- Flavor variety appears to play a role in adult cigarette smokers' switching behavior and smoking reduction

## Conclusions Continued

- Results align with the growing body of literature<sup>1</sup> suggesting flavors may play:
  - A critical role in continued ENDS use after trial
  - Moving adult cigarette smokers toward potentially less harmful tobacco products

1: e.g. Audrain-McGovern, Strasser, Wileyto 2016; Barbeau, Burba and Siegel 2013; Czoli et al. 2015; Farsalinos et al. 2013; Harrell et al. 2014; Nonnemaker et al. 2015; Pechacek et al. 2016; Shiffman et al. 2015; Simmons et al. 2016; Soule, Rosas, Nasim 2016



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